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116 Affidavit of Dr. Dennis Geiser, in the case of Abu-Ali Abdur' Rahman v. Bell, 226 F.3d 696 (6th Cir. 2000)

117 Affidavit of Carol Weihrer, in the case of Texas v. Jesus Flores, No. 877,994A

Exhibit 107: Order Granting Petitioner's Motion For Leave To Amend And To Stay And Abey Federal Proceedings

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

PERRY ALLEN AUSTIN,	§	
	§	
Petitioner,	§	
	§	
v.	§	CIVIL ACTION NO. H-04-2387
	§	
DOUGLAS DRETKE, Director, Texas Department of Criminal Justice, Institutional Division,	§	
	§	
	§	
Respondent.	§	

ORDER GRANTING PETITIONER'S MOTION FOR LEAVE TO AMEND AND TO STAY AND ABEY FEDERAL PROCEEDINGS

Petitioner Perry Allen Austin, a Texas death row inmate, has filed a petition for a writ of habeas corpus. Respondent Doug Dretke is scheduled to file an Answer to this petition. Austin now seeks leave to amend his petition to raise new claims, not previously available to him, and seeks an order to stay and abey these proceedings so that he may return to state court and exhaust his new claims.

Rule 15(a) of the Federal Rules of Civil Procedure provides that leave to amend a pleading "shall be freely given when justice so requires." Good cause has been shown for the failure to raise these claims previously, and Dretke does not oppose Austin's motion. In these circumstances, justice requires that Austin have an opportunity to amend his petition to bring his potentially meritorious claims and that these proceedings be stayed to allow him to exhaust his claims in state court.

Accordingly,

IT IS ORDERED that Petitioner's Motion for Leave to Amend to Stay and Abey (sic) Federal Proceedings (Docket Entry 36) is GRANTED.

IT IS FURTHER ORDERED that Austin shall file his successive petition in state court within 30 days of the date of this Order;

IT IS FURTHER ORDERED that Austin shall file his amended petition for writ of habeas corpus in this court within 30 days of the completion of state habeas proceedings, including any application for writ of certiorari to the United States Supreme Court;

IT IS FURTHER ORDERED that Dretke shall file an answer within 90 days after Austin files his amended petition; and

IT IS FURTHER ORDERED that Austin may respond to any Answer within 30 days after such motion is filed.

SO ORDERED.

SIGNED at Houston, Texas, on this 1st day of December, 2005.

KENNETH M. HOYT
UNITED STATES DISTRICT JUDGE

Exhibit 108: Texas, SB 60, 79th Regular Session (2005)

S.B. No. 60

AN ACT

relating to the representation of certain defendants in capital cases and to the punishment for a capital felony or other felony punishable by a term of imprisonment exceeding 99 years.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. Section 12.31, Penal Code, is amended to read as follows:

Sec. 12.31. CAPITAL FELONY. (a) An individual adjudged guilty of a capital felony in a case in which the state seeks the death penalty shall be punished by imprisonment in the institutional division for life without parole or by death. An individual adjudged guilty of a capital felony in a case in which the state does not seek the death penalty shall be punished by imprisonment in the institutional division for life without parole.

(b) In a capital felony trial in which the state seeks the death penalty, prospective jurors shall be informed that a sentence of life imprisonment without parole or death is mandatory on conviction of a capital felony. In a capital felony trial in which the state does not seek the death penalty, prospective jurors shall be informed that the state is not seeking the death penalty and that a sentence of life imprisonment without parole is mandatory on conviction of the capital felony.

SECTION 2. Subsection (c), Section 8.07, Penal Code, is amended to read as follows:

(c) No person may, in any case, be punished by death for an offense committed while the person [~~he~~] was younger than 18 [~~17~~] years.

SECTION 3. Section 508.046, Government Code, is amended to read as follows:

Sec. 508.046. EXTRAORDINARY VOTE REQUIRED. To release on parole an inmate who was convicted of [~~a capital felony or~~] an offense under Section 21.11(a)(1) or 22.021, Penal Code, or who is required under Section 508.145(c) to serve 35 calendar years before becoming eligible for release on parole, all members of the board must vote on the release on parole of the inmate, and at least two-thirds of the members must vote in favor of the release on parole. A member of the board may not vote on the release unless the member first receives a copy of a written report from the department on the probability that the inmate would commit an offense after being released on parole.

SECTION 4. Subsections (a) and (c), Section 508.145, Government Code, are amended to read as follows:

(a) An inmate under sentence of death or serving a sentence of life imprisonment without parole is not eligible for release on parole.

(c) An inmate serving a [~~life~~] sentence under Section 12.42(c)(2), Penal Code, is not eligible for release on parole until the actual calendar time the inmate has served, without consideration of good conduct time, equals 35 calendar years.

SECTION 5. Subsections (a) and (f), Section 508.146, Government Code, are amended to read as follows:

(a) An inmate, other than an inmate who is serving a sentence of death or life without parole or an inmate who has a reportable conviction or adjudication under Chapter 62, Code of Criminal Procedure, may be released on medically recommended intensive supervision on a date designated by a parole panel described by Subsection (e), except that an inmate with an instant offense that is an offense described in Section 3g, Article 42.12, Code of Criminal Procedure, may only be considered if a medical condition of terminal illness or long-term care has been diagnosed, if:

(1) the Texas Correctional Office on Offenders with Medical or Mental Impairments, in cooperation with the Correctional Managed Health Care Committee, identifies the inmate as being elderly, physically disabled, mentally ill, terminally ill, or mentally retarded or having a condition requiring long-term care;

(2) the parole panel determines that, based on the inmate's condition and a medical evaluation, the inmate does not constitute a threat to public safety; and

(3) the Texas Correctional Office on Offenders with Medical or Mental Impairments, in cooperation with the pardons and paroles division, has prepared for the inmate a medically recommended intensive supervision plan that requires the inmate to submit to electronic monitoring, places the inmate on super-intensive supervision, or otherwise ensures appropriate supervision of the inmate.

(f) An inmate who is not a citizen of the United States, as defined by federal law, who is not under a sentence of death or life

without parole, and who does not have a reportable conviction or adjudication under Chapter 62, Code of Criminal Procedure, or an instant offense described in Section 3g, Article 42.12, Code of Criminal Procedure, may be released to immigration authorities pending deportation on a date designated by a parole panel described by Subsection (e) if the parole panel determines that on release the inmate would be deported to another country and that the inmate does not constitute a threat to public safety in the other country or this country and is unlikely to reenter this country illegally.

SECTION 6. Section 1, Article 37.071, Code of Criminal Procedure, is amended to read as follows:

Sec. 1. If a defendant is found guilty in a capital felony case in which the state does not seek the death penalty, the judge shall sentence the defendant to life imprisonment without parole.

SECTION 7. Subdivision (1), Subsection (a), Section 2, Article 37.071, Code of Criminal Procedure, is amended to read as follows:

(1) If a defendant is tried for a capital offense in which the state seeks the death penalty, on a finding that the defendant is guilty of a capital offense, the court shall conduct a separate sentencing proceeding to determine whether the defendant shall be sentenced to death or life imprisonment without parole. The proceeding shall be conducted in the trial court and, except as provided by Article 44.29(c) of this code, before the trial jury as soon as practicable. In the proceeding, evidence may be presented by the state and the defendant or the defendant's counsel as to any

matter that the court deems relevant to sentence, including evidence of the defendant's background or character or the circumstances of the offense that mitigates against the imposition of the death penalty. This subdivision shall not be construed to authorize the introduction of any evidence secured in violation of the Constitution of the United States or of the State of Texas. The state and the defendant or the defendant's counsel shall be permitted to present argument for or against sentence of death. The court, the attorney representing the state, the defendant, or the defendant's counsel may not inform a juror or a prospective juror of the effect of a failure of a jury to agree on issues submitted under Subsection (c) or (e) [~~of this article~~].

SECTION 8. Subsection (e), Section 2, Article 37.071, Code of Criminal Procedure, is amended to read as follows:

(e)(1) The court shall instruct the jury that if the jury returns an affirmative finding to each issue submitted under Subsection (b) [~~of this article~~], it shall answer the following issue:

Whether, taking into consideration all of the evidence, including the circumstances of the offense, the defendant's character and background, and the personal moral culpability of the defendant, there is a sufficient mitigating circumstance or circumstances to warrant that a sentence of life imprisonment without parole rather than a death sentence be imposed.

(2) The court[~~, on the written request of the attorney representing the defendant,~~] shall:

(A) instruct the jury that if the jury answers

that a circumstance or circumstances warrant that a sentence of life imprisonment without parole rather than a death sentence be imposed, the court will sentence the defendant to imprisonment in the institutional division of the Texas Department of Criminal Justice for life without parole; and

(B) charge the jury that a defendant sentenced to confinement for life without parole under this article is ineligible for release from the department on parole. [~~in writing as follows:~~

[~~"Under the law applicable in this case, if the defendant is sentenced to imprisonment in the institutional division of the Texas Department of Criminal Justice for life, the defendant will become eligible for release on parole, but not until the actual time served by the defendant equals 40 years, without consideration of any good conduct time. It cannot accurately be predicted how the parole laws might be applied to this defendant if the defendant is sentenced to a term of imprisonment for life because the application of those laws will depend on decisions made by prison and parole authorities, but eligibility for parole does not guarantee that parole will be granted."~~]

SECTION 9. Subsection (g), Section 2, Article 37.071, Code of Criminal Procedure, is amended to read as follows:

(g) If the jury returns an affirmative finding on each issue submitted under Subsection (b) [~~of this article~~] and a negative finding on an issue submitted under Subsection (e)(1) [~~of this article~~], the court shall sentence the defendant to death. If the jury returns a negative finding on any issue submitted under

Subsection (b) [~~of this article~~] or an affirmative finding on an issue submitted under Subsection (e)(1) [~~of this article~~] or is unable to answer any issue submitted under Subsection (b) or (e) [~~of this article~~], the court shall sentence the defendant to confinement in the institutional division of the Texas Department of Criminal Justice for life imprisonment without parole.

SECTION 10. Subsections (a) and (b), Article 44.251, Code of Criminal Procedure, are amended to read as follows:

(a) The court of criminal appeals shall reform a sentence of death to a sentence of confinement in the institutional division of the Texas Department of Criminal Justice for life without parole if the court finds that there is legally insufficient evidence to support an affirmative answer to an issue submitted to the jury under Section 2(b), Article 37.071[~~, or Section 3(b), Article 37.0711, of this code or a negative answer to an issue submitted to a jury under Section 2(e), Article 37.071, or Section 3(e), Article 37.0711, of this code~~].

(b) The court of criminal appeals shall reform a sentence of death to a sentence of confinement in the institutional division of the Texas Department of Criminal Justice for life without parole if:

(1) the court finds reversible error that affects the punishment stage of the trial other than a finding of insufficient evidence under Subsection (a) of this article; and

(2) within 30 days after the date on which the opinion is handed down, the date the court disposes of a timely request for rehearing, or the date that the United States Supreme Court

disposes of a timely filed petition for writ of certiorari, whichever date is later, the prosecuting attorney files a motion requesting that the sentence be reformed to confinement for life without parole.

SECTION 11. Chapter 44, Code of Criminal Procedure, is amended by adding Article 44.2511 to read as follows:

Art. 44.2511. REFORMATION OF SENTENCE IN CAPITAL CASE FOR OFFENSE COMMITTED BEFORE SEPTEMBER 1, 1991. (a) This article applies to the reformation of a sentence of death in a capital case for an offense committed before September 1, 1991. For purposes of this subsection, an offense is committed before September 1, 1991, if every element of the offense occurred before that date.

(b) The court of criminal appeals shall reform a sentence of death to a sentence of confinement in the institutional division of the Texas Department of Criminal Justice for life if the court finds that there is legally insufficient evidence to support an affirmative answer to an issue submitted to the jury under Section 3(b), Article 37.0711.

(c) The court of criminal appeals shall reform a sentence of death to a sentence of confinement in the institutional division of the Texas Department of Criminal Justice for life if:

(1) the court finds reversible error that affects the punishment stage of the trial other than a finding of insufficient evidence under Subsection (b); and

(2) within 30 days after the date on which the opinion is handed down, the date the court disposes of a timely request for rehearing, or the date that the United States Supreme Court

disposes of a timely filed petition for writ of certiorari, whichever date is later, the prosecuting attorney files a motion requesting that the sentence be reformed to confinement for life.

(d) If the court of criminal appeals finds reversible error that affects the punishment stage of the trial only, as described by Subsection (c), and the prosecuting attorney does not file a motion for reformation of sentence in the period described by that subsection, the defendant shall receive a new sentencing trial in the manner required by Article 44.29(c).

SECTION 12. Subsection (b), Section 508.145, Government Code, is repealed.

SECTION 13. Subsection (d), Section 2, Article 11.071, Code of Criminal Procedure, is amended to read as follows:

(d) The court of criminal appeals shall adopt rules for the appointment of attorneys as counsel under this section and the convicting court may appoint an attorney as counsel under this section only if the appointment is approved by the court of criminal appeals in any manner provided by those rules. The rules must require that an attorney appointed as lead counsel under this section not have been found by a federal or state court to have rendered ineffective assistance of counsel during the trial or appeal of any capital case.

SECTION 14. Subsection (d), Article 26.052, Code of Criminal Procedure, is amended to read as follows:

(d)(1) The committee shall adopt standards for the qualification of attorneys to be appointed to represent indigent defendants in capital cases in which the death penalty is sought.

(2) The standards must require that a trial [~~an~~] attorney appointed as lead counsel to a death penalty case or an attorney appointed as lead counsel in the direct appeal of a death penalty case:

(A) be a member of the State Bar of Texas;

(B) exhibit proficiency and commitment to providing quality representation to defendants in death penalty cases;

(C) have not been found by a federal or state court to have rendered ineffective assistance of counsel during the trial or appeal of any capital case;

(D) have at least five years of experience in criminal litigation;

(E) [~~(D)~~] have tried to a verdict as lead defense counsel a significant number of felony cases, including homicide trials and other trials for offenses punishable as second or first degree felonies or capital felonies;

(F) [~~(E)~~] have trial experience in:

(i) the use of and challenges to mental health or forensic expert witnesses; and

(ii) investigating and presenting mitigating evidence at the penalty phase of a death penalty trial; and

(G) [~~(F)~~] have participated in continuing legal education courses or other training relating to criminal defense in death penalty cases.

(3) The committee shall prominently post the standards

in each district clerk's office in the region with a list of attorneys qualified for appointment.

(4) Not later than the second anniversary of the date an attorney is placed on the list of attorneys qualified for appointment in death penalty cases and each year following the second anniversary, the attorney must present proof to the committee that the attorney has successfully completed the minimum continuing legal education requirements of the State Bar of Texas, including a course or other form of training relating to the defense of death penalty cases. The committee shall remove the attorney's name from the list of qualified attorneys if the attorney fails to provide the committee with proof of completion of the continuing legal education requirements.

SECTION 15. The court of criminal appeals shall amend rules adopted under Subsection (d), Section 2, Article 11.071, Code of Criminal Procedure, as necessary to comply with that subsection, as amended by this Act, not later than January 1, 2006.

SECTION 16. A local selection committee shall amend standards previously adopted by the committee to conform with the requirements of Subsection (d), Article 26.052, Code of Criminal Procedure, as amended by this Act, not later than the 75th day after the effective date of this Act. An attorney appointed to a death penalty case on or after the 75th day after the effective date of this Act must meet the standards adopted in conformity with the amended Subsection (d), Article 26.052. An attorney appointed to a death penalty case before the 75th day after the effective date of this Act is covered by the law in effect when the attorney was

appointed, and the former law is continued in effect for that purpose.

SECTION 17. (a) The change in law made by this Act applies only to an offense committed on or after the effective date of this Act. For purposes of this section, an offense is committed before the effective date of this Act if any element of the offense occurs before the effective date.

(b) An offense committed before the effective date of this Act is covered by the law in effect when the offense was committed, and the former law is continued in effect for that purpose.

SECTION 18. This Act takes effect September 1, 2005.

President of the Senate

Speaker of the House

I hereby certify that S.B. No. 60 passed the Senate on April 14, 2005, by the following vote: Yeas 26, Nays 5; and that the Senate concurred in House amendments on May 28, 2005, by the following vote: Yeas 26, Nays 5.

Secretary of the Senate

I hereby certify that S.B. No. 60 passed the House, with amendments, on May 25, 2005, by the following vote: Yeas 121, Nays 22, two present not voting.

Chief Clerk of the House

Approved:

Date

Governor

Exhibit 109: American Society of Anesthesiologists Task Force on Intraoperative Awareness, *Practice Advisory for Intraoperative Awareness and Brain Function Monitoring*

Practice Advisory for Intraoperative Awareness and Brain Function Monitoring

A Report by the American Society of Anesthesiologists Task Force on Intraoperative Awareness[*]

PRACTICE advisories are systematically developed reports that are intended to assist decision-making in areas of patient care. Advisories provide a synthesis and analysis of expert opinion, clinical feasibility data, open forum commentary, and consensus surveys. Advisories are not intended as standards, guidelines, or absolute requirements. They may be adopted, modified, or rejected according to clinical needs and constraints.

The use of practice advisories cannot guarantee any specific outcome. Practice advisories summarize the state of the literature and report opinions derived from a synthesis of task force members, expert consultants, open forums and public commentary. Practice advisories are not supported by scientific literature to the same degree as are standards or guidelines because sufficient numbers of adequately controlled studies are lacking. Practice advisories are subject to periodic revision as warranted by the evolution of medical knowledge, technology, and practice.

Methodology

A. Definitions

Intraoperative awareness under general anesthesia is a rare occurrence, with a reported incidence of 0.1-0.2%.[1-4] Significant psychological sequelae (e.g., post traumatic stress disorder) may occur following an episode of intraoperative awareness, and affected patients may remain severely disabled

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[*] Developed by the American Society of Anesthesiologists Task Force on Intraoperative Awareness: Jeffrey L. Apfelbaum, M.D., (Chair), Chicago, Illinois; James F. Arens, M.D., Houston, Texas; Daniel J. Cole, M.D., Phoenix, Arizona; Richard T. Connis, Ph.D., Woodinville, Washington; Karen B. Domino, M.D., Seattle, Washington; John C. Drummond, M.D., San Diego, California; Cor J. Kalkman, M.D., Ph.D., Utrecht, the Netherlands; Ronald D. Miller, M.D., San Francisco, California; David G. Nickinovich, Ph.D., Bellevue, Washington; and Michael M. Todd, M.D., Iowa City, Iowa.

Supported by the American Society of Anesthesiologists under the direction of James F. Arens, M.D., Chair, Committee on Practice Parameters. A list of the references used to develop this Advisory is available by writing to the American Society of Anesthesiologists.

Address reprint requests to the American Society of Anesthesiologists: 520 N. Northwest Highway, Park Ridge, Illinois 60068-2573

for extended periods of time.[5] However, in some circumstances, intraoperative awareness may be unavoidable in order to achieve other critically important anesthetic goals.

The following terms or concepts discussed in this Advisory include: consciousness, general anesthesia, depth of anesthesia or depth of hypnosis, recall, amnesia, intraoperative awareness, and brain function monitors. Consistent definitions for these terms are not available in the literature. For purposes of this Advisory, these terms are operationally defined or identified as follows:

(1) Consciousness: Consciousness is a state in which a patient is able to process information from his or her surroundings. Consciousness is assessed by observing a patient's purposeful responses to various stimuli. Identifiers of purposeful responses include organized movements following voice commands or noxious/painful stimuli.[†] For example, opening of the eyes is one of several possible identifiers or markers of consciousness. Purposeful responses may be absent when paralysis is present as a consequence of neurological disease or the administration of a neuromuscular blocking drug.

(2) General anesthesia: General anesthesia is defined as a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation.[‡] The ability to maintain ventilatory function independently is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

(3) Depth of anesthesia: Depth of anesthesia or depth of hypnosis refers to a continuum of progressive central nervous system depression and decreased responsiveness to stimulation.

[†] Reflex withdrawal from a painful stimulus is NOT considered a purposeful response, as indicated by the "continuum of depth of sedation, definition of general anesthesia, and levels of sedation/analgesia;" American Society of Anesthesiologists, 2004.

[‡] American Society of Anesthesiologists: Continuum of depth of sedation, definition of general anesthesia, and levels of sedation/analgesia;" ASA Standards, Guidelines and Statements, 2004.

The following practice advisory was approved by the ASA House of Delegates on October 25, 2005. It should be considered final. This practice advisory will be published in a future issue of the journal *Anesthesiology.*

(4) Recall: For the purpose of this Advisory, recall is the patient's ability to retrieve stored memories. Recall is assessed by a patient's report of previous events, in particular, events that occurred during general anesthesia. *Explicit memory* is assessed by the patient's ability to recall specific events that took place during general anesthesia. *Implicit memory* is assessed by changes in performance or behavior without the ability to recall specific events that took place during general anesthesia that led to those changes.[6] A report of recall may be spontaneous or it may only be elicited in a structured interview or questionnaire. This Advisory does not address implicit memory.

(5) Amnesia: Amnesia is the absence of recall. Many anesthetic drugs produce amnesia at concentrations well below those necessary for suppression of consciousness. Anterograde amnesia is intended when a drug with amnestic properties is administered before induction of anesthesia. Retrograde amnesia is intended when a drug such as a benzodiazepine is administered after an event that may have caused or been associated with intraoperative consciousness in the hope that it will suppress memory formation and "rescue" from recall.

(6) Intraoperative awareness: Intraoperative awareness occurs when a patient becomes conscious during a procedure performed under general anesthesia and subsequently has recall of these events. For the purpose of this Advisory, recall is limited to explicit memory, and does not include the time before general anesthesia is fully induced or the time of emergence from general anesthesia, when arousal and return of consciousness are intended. Dreaming is not considered intraoperative awareness.

(7) Brain function monitors: Brain function monitors are devices that record or process brain electrical activity and convert these signals mathematically into a continuous measure typically scaled from 0 to 100. In addition to spontaneous cortical electrical activity (electroencephalogram, EEG), these devices may also record and process evoked cortical and

subcortical activity (auditory evoked potentials, or AEP) as well as electromyographic (EMG) activity from scalp muscles. For the purpose of this Advisory, only monitors purported to measure depth of anesthesia or hypnosis will be considered. Other, non-EEG/AEP/EMG devices are also available, but are not addressed by this Advisory.

B. Purposes of the Advisory

Intraoperative awareness under general anesthesia is an important clinical problem that clearly is within the foundation of training and continuing medical education in anesthesiology. The purposes of this Advisory are to identify risk factors that may be associated with intraoperative awareness, provide decision tools that may enable the clinician to reduce the frequency of unintended intraoperative awareness, stimulate the pursuit and evaluation of strategies that may prevent or reduce the frequency of intraoperative awareness, and provide guidance for the intraoperative use of brain function monitors as they relate to intraoperative awareness.

C. Focus

This Advisory focuses on the perioperative management of patients who are undergoing a procedure during which general anesthesia is administered. This Advisory is not intended for the perioperative management of minimal, moderate, or deep sedation in the OR or ICU; regional or local anesthesia without general anesthesia; monitored anesthesia care; tracheal intubation of patients or those undergoing resuscitation in emergency trauma after the administration of a neuromuscular block, or intentional intraoperative wake-up testing (e.g., for the purposes of assessing intraoperative neurologic function). In addition, this Advisory is not intended to address the perioperative management of pediatric patients.

D. Application

This Advisory is intended for use by anesthesiologists, other physicians who supervise the administration of general anesthesia, and all other individuals who administer general anesthesia.

The Advisory may also serve as a resource for other physicians and health care professionals who are involved in the perioperative management of patients receiving general anesthesia.

E. Task Force Members and Consultants

The American Society of Anesthesiologists (ASA) appointed this Task Force of 10 members to (1) review and assess the currently available scientific literature on intraoperative awareness, (2) obtain expert consensus and public opinion, and (3) develop a practice advisory. The Task Force is comprised of anesthesiologists from various geographic areas of the United States, an anesthesiologist from the Netherlands, and two methodologists from the ASA Committee on Practice Parameters.

The ASA appointed the 10 members to the Task Force because of their knowledge or expertise in the medical specialty of anesthesiology, and the development of practice parameters. The members include but are not limited to anesthesiologists with specialized knowledge or expertise in the area of neuroanesthesiology. Two of the 10 members disclosed receipt of funds from or a financial interest in a company developing or manufacturing brain function monitors, which companies have a direct financial interest in the expanded use of such monitors. Other members may have received funds from or have a financial interest in other companies, such as developers or manufacturers of anesthetics, that may be indirectly affected by the expanded use of brain function monitors. The Task Force did not request its members to disclose such interests because they were deemed too remote and speculative to present conflicts of interest.

The Task Force, in turn, sought input from consultants, many of whom who had particularized knowledge, expertise and/or interest in intraoperative awareness and brain function monitors. Such knowledge or expertise is based in part in some cases on research or investigational activities funded by a company developing or manufacturing brain function monitors. Fifty-four percent of the consultants disclosed receipt of funds from or a financial interest in a company developing or

manufacturing brain function monitors. Consultants also may have received funds from or have a financial interest in other companies that may be indirectly affected by the use of brain function monitors. The Task Force did not request its consultants to disclose such interests because they were deemed too remote and speculative to present conflicts of interest.

The Task Force used a six-step process. First, the members reached consensus on the criteria for evidence of effective perioperative interventions for the prevention of intraoperative awareness. Second, they evaluated original articles published in peer-reviewed journals relevant to this issue. Third, consultants who had expertise or interest in intraoperative awareness and who practiced or worked in diverse settings (e.g., scientists and/or physicians in academic and private practice) were asked to participate in opinion surveys on the effectiveness of various perioperative management strategies, and to review and comment on a draft of the Advisory developed by the Task Force. Fourth, additional opinions were solicited from a random sample of active members of the ASA. Fifth, the Task Force held open forums at three national and international anesthesia meetings to solicit input on the key concepts of this Advisory. Sixth, all available information was used to build consensus within the Task Force on the Advisory.

The draft document was made available for review on the ASA website, and commentary was invited via e-mail announcement to all ASA members. All submitted comments were considered by the Task Force in preparing the final draft.

F. Availability and Strength of Evidence

Practice advisories are developed by a protocol similar to that of an ASA evidence-based practice guideline, including a systematic search and evaluation of the literature. However, practice advisories lack the support of a sufficient number of adequately controlled studies to permit aggregate analyses of data with rigorous statistical techniques such as meta-analysis. Nonetheless, literature-based evidence from case reports and other descriptive studies are considered during the

development of the Advisory. This literature often permits the identification of recurring patterns of clinical practice.

As with a practice guideline, formal survey information is collected from consultants and members of the ASA. The following terms describe survey responses for any specified issue. Responses are solicited on a 5-point scale; ranging from 1 (strongly disagree) to 5 (strongly agree) with a score of 3 being equivocal. Survey responses are summarized based on median values as follows:

Strongly Agree:	Median score of 5 (At least 50% of the responses are 5)
Agree:	Median score of 4 (At least 50% of the responses are 4 or 4 and 5)
Equivocal:	Median score of 3 (At least 50% of the responses are 3, or no other response category or combination of similar categories contain at least 50% of the responses)
Disagree:	Median score of 2 (At least 50% of responses are 2 or 1 and 2)
Strongly Disagree:	Median score of 1 (At least 50% of responses are 1)

Additional information is obtained from open forum presentations and other invited and public sources. The advisory statements contained in this document represent a distillation of the current spectrum of clinical opinion and literature-based findings.[§]

Advisories

I. Preoperative Evaluation

A preoperative evaluation includes (1) obtaining a focused history (i.e., medical records, laboratory reports, patient or patient and family interview), (2) conducting a physical examination, (3) identifying patients at risk for intraoperative awareness (e.g., planned anesthetics, type of surgery), and (4) informing selected patients of the possibility of intraoperative awareness.

Descriptive studies and case reports suggest that certain patient characteristics may be associated with intraoperative awareness, including age, gender, ASA status, and drug resistance or tolerance.[4,7-

[§] Refer to appendix 1 for a summary of the advisories.

[11] Descriptive studies and case reports suggest that certain procedures (e.g., cesarean section, cardiac surgery, trauma surgery) [4,8,12-29] as well as anesthetic techniques (e.g., rapid-sequence induction, reduced anesthetic doses with or without the presence of paralysis)[2,3,9,13,16,21, 23,30-33] may be associated with an increased risk of intraoperative awareness. No studies were found that examined the clinical impact of informing the patient prior to surgery of the possibility of intraoperative awareness.

The consultants and ASA members agree that a preoperative evaluation may be helpful in identifying patients at risk for intraoperative awareness.[**] In addition, they agree that a focused preoperative evaluation to identify patients at risk of intraoperative awareness should include review of a patient's medical record, a thorough physical examination, and a patient or patient and family interview. They agree that patient characteristics that may place a patient at risk for intraoperative awareness include: substance use or abuse, limited hemodynamic reserve, and ASA status of 4 or 5. The consultants strongly agree and the ASA members agree that a history of intraoperative awareness may place a patient at risk. The consultants disagree and the ASA members are equivocal regarding whether all patients should be informed of the possibility of intraoperative awareness. The consultants strongly agree and the ASA members agree that only patients considered to be at elevated risk of intraoperative awareness should be informed of the possibility of intraoperative awareness. Finally the consultants and the ASA members disagree that informing the patient preoperatively of the risk of intraoperative awareness increases the *actual* risk of intraoperative awareness.

Advisory. The Task Force believes that some components of the preoperative evaluation may be useful in identifying a patient at increased risk for awareness. An evaluation should include, if possible, a review of a patient's medical records for previous occurrences of awareness or other potential risk factors, a patient interview to assess level of anxiety or previous experiences with anesthesia, and a physical examination. Potential risk factors to consider for patients undergoing

[**] Refer to appendix 2 for complete results of the consultant and ASA membership surveys.

general anesthesia include substance use or abuse (e.g., opioids, benzodiazepines, cocaine), a history of awareness, a history of difficult intubation or anticipated difficult intubation, chronic pain patients on high doses of opioids, cardiac surgery, Cesarean section, trauma and emergency surgery, reduced anesthetic doses in the presence of paralysis, planned use of muscle relaxants during the maintenance phase of general anesthesia, total intravenous anesthesia, the planned use of nitrous oxide-opioid anesthesia, ASA status of 4 or 5, and limited hemodynamic reserve. The consensus of the Task Force is that patients whom the individual clinician considers to be at substantially increased risk of intraoperative awareness should be informed of the possibility of intraoperative awareness when circumstances permit.

II. Preinduction Phase of Anesthesia

Issues concerned with the preinduction phase of anesthesia related to the prevention of intraoperative awareness include checking the functioning of anesthesia delivery systems, and the prophylactic administration of benzodiazepines.

Although checking the functioning of anesthesia delivery systems is standard practice, some cases of intraoperative awareness have resulted from too low concentrations of inspired volatile anesthetics or drug errors, including drug delivery errors.[8,34-39] One double-blind randomized clinical trial evaluated the efficacy of the prophylactic administration of midazolam as an anesthetic adjuvant during ambulatory procedures under total intravenous anesthesiaand reported a lower frequency of intraoperative awareness in the midazolam groups compared to the placebo group.[40] Two randomized clinical trials examined anterograde amnesia by providing pictures as stimuli after administration of midazolam but before induction of general anesthesia. Although these studies reported reduced recall in patients administered midazolam, the presence of consciousness during general anesthesia and subsequent intraoperative awareness was not examined.[41,42]

The following practice advisory was approved by the ASA House of Delegates on October 25, 2005. It should be considered final. This practice advisory will be published in a future issue of the journal *Anesthesiology.*

The consultants and ASA members strongly agree that the functioning of anesthesia delivery systems (e.g., vaporizers, infusion pumps, fresh gas flow, IV lines) should be checked to reduce the risk of intraoperative awareness. The consultants disagree, and the ASA members are equivocal that a benzodiazepine or scopolamine should be used as a component of the anesthetic to reduce the risk of intraoperative awareness for *all* patients. The consultants agree that a benzodiazepine or scopolamine should be used for patients requiring smaller dosages of anesthetics, patients undergoing cardiac surgery, and patients undergoing trauma surgery. They are equivocal regarding patients undergoing Cesarean section, emergency surgery, and with total intravenous anesthesia. The ASA members agree that a benzodiazepine or scopolamine should be used for patients requiring smaller dosages of anesthetics, patients undergoing cardiac surgery, emergency surgery, trauma surgery, and total intravenous anesthesia. They are equivocal regarding patients undergoing Cesarean section.

Advisory. Since intraoperative awareness may be caused by equipment malfunction or misuse, the Task Force believes that there should be adherence to a checklist protocol for anesthesia machines and equipment to assure that the desired anesthetic drugs and doses will be delivered. These procedures should be extended to include verification of the proper functioning of intravenous access, infusion pumps and their connections. The Task Force consensus is that the decision to administer a benzodiazepine prophylactically should be made on a case-by-case basis for selected patients (e.g., patients requiring smaller dosages of anesthetics). The Task Force cautions that delayed emergence may accompany the use of benzodiazepines.

III. Intraoperative Monitoring

Intraoperative awareness cannot be measured during the intraoperative phase of general anesthesia, since the recall component of awareness can only be determined postoperatively by obtaining information directly from the patient. Therefore, the primary issue regarding intraoperative

monitoring addressed by this Advisory is whether the use of clinical techniques, conventional monitoring systems, or brain function monitors reduce the occurrence of intraoperative awareness.

The majority of literature obtained during the search and review process did not directly address whether these techniques, systems, or monitors reduce the frequency of intraoperative awareness. However, many studies were found that report intraoperative measures or index values from monitoring activities. This literature, while not directly assessing the impact of an intervention on awareness, often reported patterns or values that occurred at identifiable times during the perioperative period with the intention of describing or predicting variations in the depth of anesthesia. Therefore, commonly reported findings from this literature are summarized below.

The literature for each intervention is presented in the following order: (1) randomized clinical trials, (2) nonrandomized comparative studies (e.g., quasi-experimental, prospective cohort studies), (3) correlational studies (e.g., correlations of index values with end-tidal concentrations of hypnotic drugs or with movement in response to noxious stimuli), (4) descriptive reports of monitor index values at particular times during a procedure; and (5) case reports of unusual or unintended benefits or harms occurring during a monitoring activity. Correlational studies often report a measure of association between two continuous variables (e.g., the correlation between index values and anesthetic drug concentrations). Other correlational measures include a prediction probability (Pk) value that provides a measure of how well a monitor or technique can differentiate between two different clinical states (e.g., response versus no response to verbal command).[43] A Pk value of 1.0 indicates perfect association between an index value and a clinical state, while a Pk value of 0.50 indicates a prediction probability equal to chance.

A. Clinical Techniques and Conventional Monitoring:

Among the clinical techniques utilized to assess intraoperative consciousness are checking for movement, response to commands, opened eyes, eyelash reflex, pupillary responses or diameters,

perspiration and tearing. Conventional monitoring systems include ASA standard monitoring[††] as well as the end-tidal anesthetic analyzer.

No clinical trials or other comparative studies were found that examine the effect of clinical techniques or conventional monitoring on the incidence of intraoperative awareness. Correlational studies reported Pk values ranging from 0.74 to 0.76 for the association between reflex or purposeful movement and indicators for depth of anesthesia.[44] One study reported a significant association between response to command and memory when continuous infusions of propofol were used as the induction anesthetic.[45] Pk values for mean arterial pressure (MAP) ranged from 0.68 to 0.94 for distinguishing a responsive state from an unresponsive state, and from 0.81 to 0.89 for distinguishing an anesthetized state from emergence following anesthesia (i.e., first response). Pk values for heart rate (HR) ranged from 0.50 to 0.82 for distinguishing a responsive state from an unresponsive state, and from 0.54 to 0.67 for emergence.[46-48] Wide ranges of mean MAP and HR values were reported during various intraoperative times. Studies reported ranges of mean MAP values as follows: before induction or baseline, 90 to 103 mmHg; at induction, 58.4 to 88 mmHg; during surgery, 78 to 102 mmHg; at emergence or end of surgery, 58.7 to 97 mmHg; and during postoperative recovery, 86 to 104mmHg. Mean HR ranges were reported as follows: before induction or baseline, 61 to 82 bpm; at induction, 55 to 67 bpm; during surgery, 74 to 82 bpm; at emergence or end of surgery, 59 to 92 bpm; and during postoperative recovery, 82 to 89 bpm.[49-56] Awareness has been reported to occur in the absence of tachycardia or hypertension.[8,23,24]

The consultants and ASA members agree that clinical techniques (e.g., checking for purposeful or reflex movement) are valuable and should be used to assess intraoperative consciousness. In addition, the consultants and ASA members agree that conventional monitoring systems (e.g, ECG,

[††] American Society of Anesthesiologists: Standards for basic anesthetic monitoring. *In* ASA Standards, Guidelines and Statements; American Society of Anesthesiologists Publication: October, 2004.

BP, HR, end-tidal anesthetic analyzer, capnography) are valuable and should be used to help assess intraoperative consciousness.

B. Brain Electrical Activity Monitoring:

Most of the devices designed to monitor brain electrical activity for the purpose of assessing anesthetic effect record electroencephalographic (EEG) activity from electrodes placed on the forehead. Systems can be subdivided into those that process spontaneous EEG and electromyographic (EMG) activity and those that acquire evoked responses to auditory stimuli (auditory evoked potential, AEP). After amplification and conversion of the analog EEG signal to the digital domain, various signal processing algorithms are applied to the frequency, amplitude, latency and/or phase relationship data derived from the raw EEG or AEP to generate a single number, often referred to as an "index" typically scaled between 100 and zero. This index represents the progression of clinical states of consciousness ('awake', 'sedated', 'light anesthesia', 'deep anesthesia'), with a value of 100 being associated with the awake state, and values of zero occurring with an isoelectric EEG (or absent middle latency AEP). These processing algorithms may either be published and in the public domain or proprietary. Detailed descriptions of the various approaches to EEG signal processing, including bispectral analysis may be found elsewhere.[57] Artifact recognition algorithms intended to avoid contaminated, and therefore spurious, 'index' values are an important component of the software in most monitors.

Although EMG activity from scalp muscles can be considered an artifact from the viewpoint of pure EEG analysis, it may be an important source of clinically relevant information. Sudden appearance of frontal (forehead) EMG activity suggests somatic response to noxious stimulation resulting from inadequate analgesia and may give warning of impending arousal. For this reason, some monitors separately provide information on the level of EMG activity.

1. Spontaneous EEG Activity Monitors.

The following practice advisory was approved by the ASA House of Delegates on October 25, 2005. It should be considered final. This practice advisory will be published in a future issue of the journal *Anesthesiology.*

Bispectral Index. Bispectral index (BIS) is a proprietary algorithm (Aspect Medical Systems) that converts a single channel of frontal EEG into an index of hypnotic level (bispectral index; BIS). BIS is available either as a separate device (BIS monitor; Aspect Medical Systems) or incorporated - under license from Aspect Medical Systems - in 'BIS modules' made by various anesthesia equipment manufacturers. To compute the BIS, several variables derived from the EEG time domain (burst-suppression analysis), frequency domain (power spectrum, bispectrum: interfrequency phase relationships) are combined into a single index of hypnotic level. BIS values are scaled from 0 to 100, with specific ranges (e.g., 40-60) reported to reflect a low probability of consciousness under general anesthesia. The weight factors for the various components in the multivariate model that generates the BIS were empirically derived from a prospectively collected database of over 1500 anesthetics. The BIS model accounts for the nonlinear stages of EEG activity by allowing different parameters to dominate the resulting BIS as the EEG changes its character with increasing plasma concentrations of various anesthetics, resulting in a linear decrease in BIS. As more data have become available and as methods and algorithms to suppress artifacts have been improved, revised iterations of the algorithm and optimized hardware have been released.

Several RCTs have compared outcomes with BIS-guided anesthetic administration versus standard clinical practice without BIS. In one RCT that enrolled 2500 patients at high risk of intraoperative awareness, explicit recall occurred in 0.17% of patients when BIS monitors were used and in 0.91% of patients managed by routine clinical practice ($p < 0.02$).[58] A small ($N = 30$) single-blinded RCT (i.e., the anesthesiologists were blinded to the recorded BIS values) compared BIS monitoring with clinical signs during cardiac surgery), and reported one episode of recall in the clinical signs group compared to no episodes in the BIS-monitored group ($p > 0.50$).[59] In other RCTs, times to awakening, first response, or eye opening and consumption of anesthetic

drugs were reduced with the use of BIS.[8,60-68]

One nonrandomized comparison of the use of BIS monitoring versus a cohort of historical controls (N = 12,771) found explicit recall occurring in 0.04% of the BIS monitored patients versus 0.18% of the historical controls ($p < 0.038$).[68] Another prospective nonrandomized cohort study (N = 19,575) designed to establish the incidence of awareness with recall during routine general anesthesia and to determine BIS values associated with intraoperative awareness events reported no statistically significant difference when BIS was used (0.18% of patients) compared to when BIS was not used (0.10% of patients). Other nonrandomized comparative studies reported higher index values upon arrival in the PACU, shorter recovery times, and lower anesthetic usage among patients monitored with BIS compared to patients not monitored with BIS.[70,71] Numerous correlational studies reported Pk values for BIS ranging from 0.72 to 1.00 for awake versus loss of response following induction with propofol (with or without opioids); and from 0.79 to 0.97 for anesthetized versus first response.[46-48,72-78] One study reported a Pk value of 0.86 for movement from electrical stimulation.[44] Wide ranges of mean BIS values have been reported during various intraoperative times. Ranges of mean BIS values were as follows: before induction or baseline, 80 to 98; at or after induction, 37 to 70; during surgery, 20 to 58; at emergence or end of surgery, 42 to 96; and during postoperative recovery, 64 to 96.[50,51,54-56,79-110] Several case reports indicate that intraoperative events unrelated to titration of anesthetic agents can produce rapid changes in BIS values, e.g., cerebral ischemia or hypoperfusion, gas embolism, unrecognized hemorrhage, inadvertent blockage of anesthesia drug delivery.[111-119] Other case reports suggest that routine intraoperative events (e.g., administration of depolarizing muscle relaxants, activation of electromagnetic equipment or devices, patient warming or planned hypothermia) may interfere with BIS functioning.[120-128] Two case reports were found that reported patients experiencing intraoperative awareness in spite of monitored values indicating an

adequate depth of anesthesia.[129,130] Finally, still other case reports suggested that certain patient conditions may affect BIS values.[131-133]

Entropy. Entropy (GE Healthcare Technologies) describes the irregularity, complexity, or unpredictability characteristics of a signal. A single sine wave represents a completely predictable signal (entropy = 0), whereas noise from a random number generator represents entropy = 1. The algorithm for calculation of entropy in the EEG signal (as incorporated in the Datex-Ohmeda S/5 entropy Module) is in the public domain and detailed descriptions have recently been published.[134]

Entropy is independent of absolute scales such as the amplitude or the frequency of the signal. The commercially available Datex-Ohmeda module calculates entropy over time windows of variable duration and reports two separate entropy values. State entropy (SE) is an index ranging from zero to 91 (awake), computed over the frequency range from 0.8 Hz to 32 Hz, reflecting the cortical state of the patient. Response Entropy (RE) is an index ranging from zero to 100 (awake) computed over a frequency range from 0.8 Hz to 47 Hz, containing the higher EMG-dominated frequencies, and will thus also respond to the increased EMG activity resulting from inadequate analgesia. No clinical trials or other comparative studies were found that examine the impact of entropy monitoring on the incidence of intraoperative awareness. One clinical trial reported reduced times to eye opening, response to command, and consumption of anesthetic drugs with the use of entropy monitoring.[135]

Correlational studies report the following Pk values for loss of consciousness: for RE, 0.83 to 0.97; for SE, 0.81 to 0.90.[45,136-137] For anesthetized versus first response, the following Pk values are reported: for RE, 0.85; and for SE, 0.82.[46] Ranges of mean RE and SE values were as follows: before induction or baseline, 98 (RE) and 89 to 91 (SE); during surgery, 34 to 52 (RE) and 50 to 63 (SE); and at emergence or end of surgery, 96 (RE) and 85 (SE).[52,135,138,139]

The following practice advisory was approved by the ASA House of Delegates on October 25, 2005. It should be considered final. This practice advisory will be published in a future issue of the journal *Anesthesiology.*

Narcotrend. The Narcotrend (MonitorTechnik) is derived from a system developed for the visual classification of the EEG patterns associated with various stages of sleep. After artifact exclusion and Fourier transformation, the original electronic algorithm classified the raw (frontal) EEG according to the following system: A (awake), B (sedated), C (light anesthesia), D (general anesthesia), E (general anesthesia with deep hypnosis), F (general anesthesia with increasing burst suppression). The system included a series of sub-classifications resulting in a total of 14 possible sub-stages: A, B0–2, C0–2, D0–2, E0–1, and F0–1.[140] In the most recent iteration of the Narcotrend software (version 4.0), the alphabet-based scale has been "translated" into a dimensionless index, the Narcotrend index, scaled from zero (deeply anesthetized) to 100 (awake), with the stated intention of producing a scale quantitatively similar to the BIS index.

No clinical trials or other comparative studies were found that examine the impact of Narcotrend monitoring on the incidence of intraoperative awareness. One RCT has compared the use of Narcotrend-controlled versus clinically controlled anesthetic administration and found a shorter recovery time in the Narcotrend group (i.e., opened eyes) after termination of anesthesia.[63] Pk values for Narcotrend ranged from 0.93 to 0.99 for awake versus loss of response following induction with propofol combined with an opioid, and from 0.94 to 0.99 for anesthetized versus first response.[47,48] Reported mean Narcotrend values are as follows: after induction (loss of response), 72 to 80; and at emergence or end of surgery (spontaneously opened eyes), 80.[73]

Patient State Analyzer. The Patient State Index, or PSI (Physiometrix) is derived from a 4-channel EEG. The derivation of the PSI is based on the observation that there are reversible spatial changes in power distribution of quantitative EEG at loss and return of consciousness. The Patient State Index (PSI) has a range of 0 to 100, with decreasing values indicating decreasing levels of consciousness or increasing levels of sedation, similar to BIS, Entropy and Narcotrend. The PSI algorithm was constructed using stepwise, discriminant analysis based on

multivariate combinations of quantitative EEG variables, derived after Fourier transformation of the raw EEG, and found to be sensitive to changes in the level of anesthesia.

No clinical trials or other comparative studies were found that examine the impact of PSI monitoring on the incidence of intraoperative awareness. One correlational study reported a Pk value of 0.70 for predicting response to command, with a sensitivity of 85.6% and specificity of 38.8%,[77] and another study reported a significant correlation of the PSI with unconsciousness.[141] Reported mean PSI values are as follows: before induction or baseline, 92; during surgery, 32; at emergence or end of surgery, 53; and during postoperative recovery, 81.[141]

SNAP index. The SNAPII (Everest Biomedical Instruments) calculates a "SNAP index" from a single channel of EEG. The index calculation is based on a spectral analysis of EEG activity in the 0-18 Hz and 80-420 Hz frequency ranges, and a burst suppression algorithm. There are no published data on the actual algorithm used to calculate the SNAP index, which is based on a composite of both low (0-40 Hz) and high (80-420 Hz) frequency components.

No clinical trials or other comparative studies were found that examine the impact of SNAP monitoring on the incidence of intraoperative awareness. One correlational study was found that reported a mean SNAP index of 71 to be predictive of a loss of consciousness in 95% of elective surgery patients.[142]

Danmeter Cerebral State Monitor/Cerebral State Index. The Danmeter CSM is a handheld device that analyzes a single channel EEG and presents a cerebral state 'index' scaled from 0-100. In addition, it also provides EEG suppression percentage and a measure of EMG activity (75-85 Hz).

No published literature was found that examined the impact of Danmeter CSM monitoring on the incidence of intraoperative awareness.

2. Evoked Brain Electrical Activity Monitors.

The following practice advisory was approved by the ASA House of Delegates on October 25, 2005. It should be considered final. This practice advisory will be published in a future issue of the journal *Anesthesiology.*

AEP Monitor/2 (Danmeter). Auditory evoked potentials (AEP) are the electrical responses of the brainstem, the auditory radiation and the auditory cortex to auditory sound stimuli (clicks) delivered via headphones. The effects of anesthetics on AEP have been studied since the early 1980s.[143-145] The brainstem response is relatively insensitive to anesthetics while early cortical responses, known as the middle-latency AEP (MLAEP) change predictably with increasing concentrations of both volatile and intravenous anesthetics. The typical AEP response to increasing anesthetic concentrations is increased latency and decreased amplitude of the various waveform components. These signals are extremely small (less than one microvolt) necessitating extraction from the spontaneous EEG using signal averaging techniques. Prior to recent innovations, signal averaging was relatively time consuming (several minutes per averaged waveform). More recent signal filtering advances have resulted in an instrument (A-Line) that can record and rapidly update a single channel of AEP from forehead electrodes. From a mathematical analysis of the AEP waveform, the device generates an 'AEP-index' that provides a correlate of anesthetic concentration. The AEP index, or AAI, is scaled from 0 to 100. In contrast to many EEG indices, the AAI corresponding with low probability of consciousness is less than 25, rather than the higher numeric thresholds associated with the other monitors. The device is FDA approved but is not currently marketed in North America.

RCTs that compared MLAEP monitoring (e.g., to titrate anesthetics) to standard clinical practice without MLAEP reported reduced times to eye opening or orientation.[63,64,146] A Pk value of 0.79 was reported for loss of eyelash reflex following induction with propofol and an opioid,[74] and Pk values of 0.63 and 0.66 were reported for responsiveness following discontinuation of remifentanil or sevoflurane, respectively.[147] One study reported a Pk value of 0.87 for movement,[148] and another study reported a Pk value of 0.99 for awareness after LMA insertion,[149] Descriptive studies reported ranges of mean values as follows: before induction or baseline, 73.5

to 85; at or after induction, 33.4 to 61; during surgery, 21.1 to 37.8; at emergence or end of surgery, 24.6 to 40; and during postoperative recovery, 89.7.[74,80,144,150-151]

C. Consultant and ASA Member Survey Findings.

Consultants who participated in this Advisory typically either had a particular knowledge or an expressed interest in intraoperative awareness and brain function monitors. The majority of these consultants disclosed receipt of funds from or a financial interest in a company developing or manufacturing brain function monitors. Consultants were not asked to disclose similar relationships with other companies that may be indirectly affected by the use of brain function monitors. ASA members were randomly selected from a list of active members of the society.

The consultants and ASA members disagree that a brain electrical activity monitor is valuable and should be used to reduce the risk of *intraoperative awareness* for *all* patients. The consultants and ASA members disagree that a brain electrical activity monitor is valuable and should be used to reduce the risk of intraoperative awareness for *no* patient. The consultants agree that a brain electrical activity monitor should be used for patients with conditions that may place them at risk, patients requiring smaller doses of general anesthetics, trauma surgery, Cesarean section, and total intravenous anesthesia. They are equivocal regarding the use of brain electrical activity monitoring for cardiac surgery and emergency surgery. The ASA members agree with the use of such monitors for patients with conditions that may place them at risk, patients requiring smaller doses of general anesthetics, and patients undergoing cardiac surgery. They are equivocal regarding the use of these monitors for patients undergoing Cesarean section, emergency surgery, trauma surgery, and total intravenous anesthesia.

The consultants and ASA members disagree that a brain electrical activity monitor is valuable and should be used to assess intraoperative *depth of anesthesia* for *all* patients. The consultants and ASA members disagree with the statement that “a brain electrical activity monitor is valuable and

should be used to assess intraoperative depth of anesthesia for *no* patient." The consultants agree that a brain electrical activity monitor should be used to assess intraoperative depth of anesthesia for selected patients. The ASA members agree with the use of brain electrical activity monitors for patients with conditions that may place them at risk and patients requiring smaller doses of general anesthetics. They are equivocal regarding the use of such monitors for patients undergoing cardiac surgery, Cesarean section, emergency surgery, trauma surgery, and total intravenous anesthesia.

Advisory. Intraoperative monitoring of depth of anesthesia, for the purpose of minimizing the occurrence of awareness, should rely on multiple modalities, including clinical techniques (e.g., checking for clinical signs such as purposeful or reflex movement) and conventional monitoring systems (e.g., ECG, BP, HR, end-tidal anesthetic analyzer, capnography). The use of neuromuscular blocking drugs may mask purposeful or reflex movements, and adds additional importance to the use of monitoring methods that assure the adequate delivery of anesthesia.

Brain function monitors are dedicated to the assessment of the effects of anesthetics on the brain, and provide information that correlates with some depth of anesthesia indicators, such as plasma concentrations of certain anesthetics (e.g., propofol). In general, the indices generated by these monitors vary in parallel with other established correlates of depth of anesthesia, although the values generated by individual devices in any given anesthetic state differ among the various monitoring technologies. In addition, the values generated by individual devices in the face of a given depth of anesthesia achieved by different combinations of anesthetic drugs (e.g., with or without opioids) will also differ. In other words, a specific numerical value may not correlate with a specific depth of anesthesia. Furthermore, the measured values do not have uniform sensitivity across different anesthetic drugs or types of patients. As with other monitors, common occurrences in the OR may introduce artifacts into the values derived by these monitors (e.g., electrocautery, lasers, warming devices).

The general clinical applicability of these monitors in the prevention of intraoperative awareness has not been established. While a single randomized clinical trial reported a decrease in the frequency of awareness in high-risk patients, there is insufficient evidence to justify a standard, guideline, or absolute requirement that these devices be used to reduce the occurrence of intraoperative awareness in high-risk patients undergoing general anesthesia. In addition, there is insufficient evidence to justify a standard, guideline, or absolute requirement that these devices be used to reduce the occurrence of intraoperative awareness for any other group of patients undergoing general anesthesia.

It is the consensus of the Task Force that brain function monitoring is not routinely indicated for patients undergoing general anesthesia, either to reduce the frequency of intraoperative awareness or to monitor depth of anesthesia. This consensus is based, in part, on the state of the literature and survey responses from the consultants and ASA membership, who generally disagree with the following statements: "Brain function monitors are valuable and should be used to reduce the risk of intraoperative awareness for all patients under general anesthesia," and "Brain function monitors are valuable and should be used when possible to assess intraoperative depth of anesthesia for all patients under general anesthesia" (see above and tables 1 and 2).

It is the consensus of the Task Force that the decision to use a brain function monitor should be made on a case-by-case basis by the individual practitioner for selected patients (e.g., light anesthesia). This consensus is based, in part, on the state of the literature and survey response patterns from consultants and ASA members regarding specific risk factors (see above and tables 1 and 2). The Task Force cautions that maintaining low brain function monitor values in an attempt to prevent intraoperative awareness may conflict with other important anesthesia goals (e.g., preservation of vital organ functions, minimizing the risks of aggravating existing co-morbidities [152]). It is the opinion of the Task Force that brain function monitors currently have the status of the many

other monitoring modalities that are currently used in selected situations at the discretion of individual clinicians.

IV. Intraoperative and Postoperative Interventions

Intraoperative and postoperative interventions include: (1) the intraoperative administration of benzodiazepines to patients who may have become conscious, (2) providing a postoperative structured interview to patients to define the nature of the episode after an episode of intraoperative awareness has been reported, (3) providing a postoperative questionnaire to patients to define the nature of the episode, and (4) offering postoperative counseling or psychological support.

No studies were found that evaluated the efficacy of the intraoperative administration of benzodiazepines to patients who have unexpectedly become conscious in reducing the occurrence of awareness. Two randomized clinical trials examined retrograde amnesia by providing pictures as stimuli to awake patients before administration of midazolam and induction of general anesthesia. The studies reported no evidence of retrograde amnesia.[41,42] However, these studies did not examine the effect of administering a benzodiazepine to patients after the apparent occurrence of consciousness during general anesthesia.

Although several studies have applied structured interviews and questionnaires to obtain additional information about reported incidences of intraoperative awareness,[4,11,26,28,153-157] no studies were found that demonstrated improvements in patient well-being or psychological state following such interactions. No studies were found that followed up on the efficacy of counseling or psychological support provided to patients who experienced a documented incidence of intraoperative awareness.

The consultants are equivocal and ASA members agree that benzodiazepines or scopolamine should be administered intraoperatively to prevent awareness after a patient has unexpectedly become conscious. The consultants strongly agree, and the ASA members agree that, once an episode of

intraoperative awareness has been reported, a structured interview should be conducted to define the nature of the episode. Both the consultants and ASA members are equivocal regarding whether a questionnaire should be given to define the nature of the episode. The consultants strongly agree, and the ASA members agree that, in documented cases of intraoperative awareness, patients should be offered counseling or psychological support. Finally, the consultants strongly agree, and the ASA members agree that, in documented cases of intraoperative awareness, an occurrence report concerning the event should be completed for the purpose of quality management.

Advisory. The Task Force consensus is that the decision to administer a benzodiazepine intraoperatively after a patient unexpectedly becomes conscious should be made on a case-by-case basis. . This consensus is based, in part, on the state of the literature and on responses from the Consultants and ASA members who generally agree with the following statement: "Benzodiazepines or scopolamine should be administered intraoperatively to prevent awareness after a patient has unexpectedly become conscious." However, the Task Force believes that evidence from the literature is not sufficient to provide guidance regarding this issue. Finally, the Task Force cautions that the use of scopolamine may result in unintended side-effects (e.g., emergence delirium).

Practitioners should speak with patients who report recall of intraoperative events to obtain details of the event and to discuss possible reasons for its occurrence.[⌗⌗] A questionnaire or structured interview may be used to obtain a detailed account of the patient's experience. Once an episode of intraoperative awareness has been reported, an occurrence report concerning the event should be completed for the purpose of quality management. Finally, the patient should be offered counseling or psychological support.

[⌗⌗] Refer to the ASA Director of Communications at 847-825-5586 for further information and guidance.

The following practice advisory was approved by the ASA House of Delegates on October 25, 2005. It should be considered final. This practice advisory will be published in a future issue of the journal *Anesthesiology.*

Appendix 1: Summary of Practice Advisory

Preoperative Evaluation

- Review patient medical records for potential risk factors
  - Substance use or abuse
  - Previous episode of intraoperative awareness
  - History of difficult intubation or anticipated difficult intubation
  - Chronic pain patients on high doses of opioids
  - ASA status 4-5
  - Limited hemodynamic reserve
- Interview patient
  - Assess level of anxiety
  - Obtain information regarding previous experiences with anesthesia
- Determine other potential risk factors
  - Cardiac surgery
  - Cesarean section
  - Trauma surgery
  - Emergency surgery
  - Reduced anesthetic doses in the presence of paralysis
  - Planned use of muscle relaxants during the maintenance phase of general anesthesia
  - Planned use of nitrous oxide-opioid anesthesia
- Patients whom the individual clinician considers to be at substantially increased risk of intraoperative awareness should be informed of the possibility of intraoperative awareness when circumstances permit

Preinduction Phase of Anesthesia

- Adhere to a checklist protocol for anesthesia machines and equipment to assure that the desired anesthetic drugs and doses will be delivered
- Verifiy the proper functioning of intravenous access, infusion pumps and their connections, including the presence of appropriate back-flow check valves
- The decision to administer a benzodiazepine prophylactically should be made on a case-by-case basis for selected patients (e.g., patients requiring smaller dosages of anesthetics)

Intraoperative Monitoring

- Use multiple modalities to monitor depth of anesthesia
  - Clinical techniques (i.e., checking for purposeful or reflex movement)
    - Neuromuscular blocking drugs may mask purposeful or reflex movement
  - Conventional monitoring systems (e.g., ECG, BP, HR, end-tidal anesthetic analyzer, capnography
  - Brain function monitoring
    - Not routinely indicated for general anesthesia patients
    - The decision to use a brain function monitor should be made on a case-by-case basis by the individual practitioner for selected patients (e.g., light anesthesia)

Intraoperative and Postoperative Management

The following practice advisory was approved by the ASA House of Delegates on October 25, 2005. It should be considered final. This practice advisory will be published in a future issue of the journal *Anesthesiology.*

- The decision to administer a benzodiazepine intraoperatively after a patient unexpectedly becomes conscious should be made on a case-by-case basis
- Speak with patients who report recall of intraoperative events to obtain details of the event and to discuss possible reasons for its occurrence
- A questionnaire or structured interview may be used to obtain a detailed account of the patient's experience
- Once an episode of intraoperative awareness has been reported, an occurrence report concerning the event should be completed for the purpose of quality management
- Offer counseling or psychological support to those patients who report an episode of intraoperative awareness

The following practice advisory was approved by the ASA House of Delegates on October 25, 2005. It should be considered final. This practice advisory will be published in a future issue of the journal *Anesthesiology.*

Appendix 2: Literature Review and Consensus-Based Evidence

For this Advisory, a literature review was used in combination with opinions obtained from experts and other sources (e.g., professional society members, open forums, web-based postings) to provide guidance to practitioners regarding intraoperative awareness. Both the literature review and opinion data were based on *evidence linkages*, consisting of directional statements about relationships between specific perioperative interventions and intraoperative awareness. The interventions for the evidence linkages are listed below:

Preoperative Evaluation

- Focused history (i.e., medical records, patient interview, physical exam)
- Patient characteristics associated with risk of awareness
- Procedures associated with higher risk of intraoperative awareness
- Anesthetic techniques may be associated with higher risk of intraoperative awareness
- Informing patients of the possiblity of intraoperative awareness

Preinduction Phase of Anesthesia

- Check anesthesia delivery systems to reduce errors
- Prophylactic administration of benzodiazepines as co-anesthetics

Intraoperative Monitoring

- Commonly used clinical techniques
- Conventional monitoring systems
- Brain function monitors
  - Spontaneous electrical activity (EEG/EMG)
    - Bispectral index (BIS)
    - Danmeter Cerebral State Monitor/Cerebral State Index
    - Entropy
    - Narcotrend
    - Patient state analyzer (PSA)
    - SNAP index
  - Evoked electrical activity (auditory evoked potential monitoring)
    - AEP Monitor/2

Intraoperative and Postoperative Interventions

- Intraoperative use of benzodiazepines for unexpected consciousness
- Structured interview of patients who report recall of intraoperative events
- Questionnaire administered to patients who report recall of intraoperative events
- Patient counseling for patients who report recall of intraoperative events

A. State of the Literature.

A study or report that appears in the published literature is included in the development of an advisory if the study: (1) is related to one of the specified linkage statements, (2) reports a finding or set of findings that can be tallied or measured (e.g., articles that contain only opinion are not included), and (3) is the product of an original investigation or report (i.e., review articles or follow-up studies that summarize previous findings are not included).

For the literature review, potentially relevant studies were identified via electronic and manual searches of the literature. The electronic search covered a 40-year period from 1966 through 2005. The manual search covered a 36-year period of time from 1970 through 2005. Over 1500 citations were initially identified, yielding a total of 711 non-overlapping articles that addressed topics related to the evidence linkages and met our criteria for inclusion. Following review of the articles, 389 studies did not provide direct evidence, and were subsequently eliminated. A total of 322 articles contained direct linkage-related evidence. No evidence linkage contained enough studies with well-defined experimental designs and statistical information to conduct a quantitative analysis (i.e., meta-analysis).

Interobserver agreement among Task Force members and two methodologists was established by interrater reliability testing. Agreement levels using a kappa (κ) statistic for two-rater agreement pairs were as follows: (1) type of study design, $\kappa = 0.60$ to 0.85; (2) type of analysis, $\kappa = 0.60$ to 0.93; (3) evidence linkage assignment, $\kappa = 0.77$ to 0.88; and (4) literature inclusion for database, $\kappa = 0.76$ to 1.00. Three-rater chance-corrected agreement values were: (1) study design, Sav = 0.82, Var (Sav) = 0.007; (2) type of analysis, Sav =0.73, Var (Sav) = 0.008; (3) linkage assignment, Sav = 0.69 Var (Sav) = 0.012; (4) literature database inclusion, Sav = 0.84, Var (Sav) = 0.014. These values represent moderate-to-high levels of agreement.

The primary focus of this Advisory was to examine studies with hypothesis-driven research designs, such as RCTs, that examined the effect of an intervention (such as a brain function monitor) on reducing the occurrence or frequency of intraoperative awareness. To date, only two randomized controlled trials were found that reported intraoperative awareness as the primary study endpoint.[55,56] Additional controlled trials will be necessary before data from published literature can be aggregated to provide a basis for quantitative evidence (i.e., meta-analysis).

Several other RCTs were reviewed that reported primary outcomes other than intraoperative awareness, including emergence time, consumption of anesthetic drugs and recovery characteristics. In addition, many other published studies applied non-hypothesis driven research designs to obtain non-causal or indirect data. For example, descriptive literature (i.e., reports of frequency or incidence) may provide an indication of the scope of the problem. Correlational or predictive data provides information regarding the direction and strength of association of values obtained from patient monitoring devices with other intraoperative measures such as blood concentrations of anesthetic drugs, time to loss of eyelash reflex, and time to awakening. Case reports are typically employed as a forum for reporting and recognizing unusual or unintended benefits or harms. Often, case reports, as well as descriptive or correlational data provide useful hypotheses-generating information that may stimulate additional causal examination of the topic of intraoperative awareness.

Future studies should focus on prospective methodologies, when possible, that utilize traditional hypothesis testing techniques. Use of the following methodological procedures for assessing the impact of interventions for intraoperative awareness is recommended: (1) comparison studies assessing the efficacy of one technique versus other techniques; (2) random assignment to treatment groups with blinding if appropriate; and (3) full reporting of sample size, effect size estimates, test scores, measures of variability, and p-values. The Task Force recognizes that conducting such

studies may be difficult and expensive, because intraoperative awareness is a very low incidence event. The required sample size for a RCT to test the impact of an intervention (e.g., brain function monitor) on the incidence of intraoperative awareness is invariably large. The Task Force also recognizes that, with low incidence data, a difference in the recording of one or two cases of intraoperative awareness can affect the statistical significance of study findings.

Limiting the study to patient subgroups thought to have a higher risk for intraoperative awareness (e.g., cardiac surgery, cesarean section, emergency trauma surgery) may allow for a smaller sample size and provide useful information regarding these subgroups. However, the Task Force recognizes that the generalizability of these findings to the larger population of general anesthesia patients may be limited.

B. Consensus-Based Evidence.

Consensus was obtained from multiple sources, including: (1) survey opinion from Consultants who were selected based on their knowledge or expertise in intraoperative awareness, (2) survey opinions from a randomly selected sample of active members of the American Society of Anesthesiologists, (3) testimony from attendees of three open forums held at national anesthesia meetings,[§§] (4) internet commentary, and (5) Task Force opinion and interpretation. The survey rate of return was 60% (N = 57/95) for Consultants, and 30% (N=151/500) for the ASA membership. Survey results are presented in the text of the document and in tables 1 and 2.

Ninety-one percent of the consultants and 72% of the ASA members indicated that they had personally used a brain function device in the past. Fifty-seven percent of the consultants indicated that they make use in their current practice of a brain function device either always (11.1%), frequently (20.4%), or sometimes (25.9%). Thirty-six percent of the ASA members

[§§] American Society of Anesthesiologists, Annual Meeting, October 25, 2004 in Las Vegas, NV; International Anesthesia Research Society, 79th Clinical and Scientific Congress, March 12, 2005 in Honolulu, HI; and Association of University Anesthesiologists 52nd Annual Meeting, May 6, 2005 in Baltimore, MD.

indicated that they make use in their current practice of a brain function device either always (6.0%), frequently (13.4%), or sometimes (16.8%).

The Consultants were also asked to indicate which, if any, of the evidence linkages would change their clinical practices if the Advisory was instituted (table 3). The rate of return was 18% (N = 17/95). The percent of responding Consultants expecting *no change* associated with each linkage were as follows: preoperative evaluation - 82%; informing patients of the possibility of intraoperative awareness - 65%; check anesthesia delivery systems - 94%; prophylactic use of benzodiazepines as co-anesthetics - 100%; use of clinical techniques to monitor for intraoperative awareness - 94%; use of conventional monitoring systems to monitor for intraoperative awareness - 100%; use of brain function monitors to monitor for intraoperative awareness - 59%; intraoperative use of benzodiazepines for uuunexpected consciousness - 100%; use of a structured interview for patients who report recall of intraoperative events - 41%; use of a questionnaire for patients who report recall of intraoperative events - 53% and counseling for patients who report recall of intraoperative events - 76%. Seventy-one percent of the respondents indicated that the Advisory would have *no effect* on the amount of time spent on a typical case. Four respondents (24%) indicated that there would be an increase in the amount of time they would spend on a typical case with the implementation of this Advisory. The amount of increased time anticipated by these respondents ranged from 1 to 20 minutes.

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Table 1. Consultant Survey Responses [***]

		Percent Responding to Each Item				
Preoperative evaluation:	N	Strongly Agree	Agree	Uncertain	Disagree	Strongly Disagree
1. Helpful to identify pts at risk of intraoperative awareness	57	31.6	43.9*	7.0	10.5	7.0
2. A preop eval should include:						
Review of medical records	48	41.7	45.8*	4.2	6.3	2.1
A physical examination	47	21.3	34.0*	17.0	25.5	2.1
A patient/family interview	48	39.6	35.4*	14.6	8.3	2.1
3. Potential patient risk factors:						
Substance use or abuse	54	38.9	42.6*	5.6	13.0	0.0
Pt history of intraop awareness	55	52.7*	29.1	10.9	7.3	0.0
Limited hemodynamic reserve	54	38.9	40.7*	13.0	7.4	0.0
ASA status of 4 or 5	54	24.1	48.1*	20.4	7.1	0.0
4. Procedures/ anesthetic techniques that may place a patient at risk for intraop awareness:						
Cesarean section under GA, cardiac surgery, trauma, emergency surgery	57	75.4*	24.6	0.0	0.0	0.0
Planned use of reduced doses of anesthetics in the presence of paralysis	56	66.1*	25.0	5.4	1.8	1.8
Planned use of muscle relaxants for maintenance	57	26.4	45.6*	8.8	17.5	1.8
Planned use of total intravenous anesthesia	57	10.5	33.3	24.6*	21.1	10.5
Planned use of volatile anesthetics	57	3.5	5.3	12.3	57.9*	21.1
Planned use of nitrous oxide-narcotic anesthesia	57	29.8	35.1*	14.0	19.3	1.8
Preoperative or intraoperative use of beta-blockers under general anesthesia	57	5.3	35.1	26.3*	29.8	3.5
Rapid-sequence induction	57	5.3	29.8	19.3*	42.1	3.5
5. All pts should be informed of the possibility of intraop awareness	57	10.5	31.6	5.3	42.1*	10.5
6. Only patients considered to be at elevated risk of intraop awareness should be informed of the possibility of intraop awareness	40	17.5	60.0*	5.0	7.5	10.0

[***] N = the number of consultants who responded to each item. An astrisk beside a percentage score indicates the median.

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	N	Strongly Agree	Agree	Uncertain	Disagree	Strongly Disagree
7. Informing the pt preoperatively of the risk of intraop awareness increases the actual risk of intraoperative awareness	53	3.8	5.7	30.2	35.8*	24.5
Preinduction activities:						
8. The functioning of anesthesia delivery systems should be checked preoperatively to reduce the risk of intraop awareness	57	77.2*	17.5	1.8	3.5	0.0
9. A benzodiazepine or scopolamine should be used as a component of the anesthetic to reduce the risk of intraop awareness:						
For all patients under GA	54	7.4	24.1	1.9	33.3*	33.3
For no patients under GA	54	3.7	3.7	3.7	46.3*	42.6
For pts with conditions that may place them at risk for intraop awareness	53	20.8	58.5*	7.5	7.5	5.7
For patients requiring smaller dosages of general anesthetics (“light anesthesia”)	53	17.0	43.4*	11.3	20.8	7.5
For patients undergoing cardiac surgery	54	22.2	44.4*	11.1	16.7	5.6
For patients undergoing Cesarean section under GA	54	7.4	29.6	20.4*	31.5	11.1
For patients undergoing emergency surgery under GA	53	15.1	30.2	20.8*	28.3	5.7
For patients undergoing trauma surgery under GA	54	16.7	35.2*	20.4	22.2	5.6
For patients undergoing total intravenous anesthesia	54	16.7	31.5	18.5*	24.1	9.3
Intraoperative Monitoring:						
10. Commonly used clinical techniques (e.g., checking for purposeful or reflex movement) are valuable and should be used to detect intraop consciousness	53	18.9	47.2*	5.7	18.9	9.4
11. Conventional monitoring systems are valuable and should be used to detect intraoperative consciousness	53	22.6	41.5*	5.7	24.5	5.7

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	N	Strongly Agree	Agree	Uncertain	Disagree	Strongly Disagree
12. Brain function monitors are valuable and should be used to reduce the risk of intraoperative awareness:						
For all patients under GA	57	7.0	21.1	19.3	15.8*	36.8
For no patients under GA	56	3.6	7.1	14.3	35.7*	39.3
For pts with conditions that may place them at risk for intraop awareness	57	36.8	26.3*	14.0	14.0	8.8
For patients requiring smaller dosages of general anesthetics (“light anesthesia”)	56	26.8	32.1*	14.3	19.6	7.1
For patients undergoing cardiac surgery	57	28.1	21.1	26.3*	14.0	10.5
For patients undergoing Cesarean section under GA	57	31.6	21.1*	21.1	17.5	8.8
For patients undergoing emergency surgery under GA	57	21.1	28.1	24.6*	17.5	8.8
For patients undergoing trauma surgery under GA	57	26.3	24.6*	24.6	15.8	8.8
For patients undergoing total intravenous anesthesia	56	16.1	39.3*	23.2	14.3	7.1
13. Brain function monitors are valuable and should be used when possible to assess intraoperative depth of anesthesia:						
For all patients under GA	56	12.5	21.4	10.7	14.3*	41.1
For no patients under GA	54	9.3	5.6	9.3	37.0*	38.9
For pts with conditions that may place them at risk for intraop awareness	56	33.9	30.4*	8.9	14.3	12.5
For patients requiring smaller dosages of general anesthetics (“light anesthesia”)	56	28.6	35.7*	10.7	10.7	14.3
For patients undergoing cardiac surgery	56	26.8	28.6*	16.1	14.3	14.3
For patients undergoing Cesarean section under GA	56	28.6	32.1*	12.5	12.5	14.3

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	N	Strongly Agree	Agree	Uncertain	Disagree	Strongly Disagree
For patients undergoing emergency surgery under GA	57	21.1	36.8*	10.5	17.5	14.0
For patients undergoing trauma surgery under GA	57	22.8	38.6*	10.5	14.0	14.0
For patients undergoing total intravenous anesthesia	57	26.3	35.1*	17.5	8.8	12.3
Intraoperative & Postoperative Interventions:						
14. Benzodiazepines or scopolamine should be administered intraoperatively to prevent awareness after a pt has unexpectedly become conscious	57	21.1	26.3	15.8*	21.1	15.8
15. Once an episode of intraoperative awareness has been reported, a structured interview should be conducted to define the nature of the episode	57	63.2*	31.5	1.8	0.0	0.0
16. Once an episode of intraop awareness has been reported, a questionnaire should be given to define the nature of the episode	57	10.5	19.3	36.8*	28.1	5.3
17. Once an episode of intraop awareness has been reported and documented, the pt should be offered counseling or psychological support	56	69.6*	25.0	5.4	0.0	0.0
18. Once an episode of intraop awareness has been reported, an occurrence report concerning the event should be completed for the purpose of quality management	57	54.4*	40.4	0.0	5.3	0.0

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Table 2. ASA Member Survey Responses[†††]

		Percent Responding to Each Item				
Preoperative evaluation:	N	Strongly Agree	Agree	Uncertain	Disagree	Strongly Disagree
1. Helpful to identify pts at risk of intraoperative awareness	146	27.4	46.6*	14.4	10.3	1.4
2. A preop eval should include:						
Review of medical records	121	38.8	47.9*	7.4	5.0	0.8
A physical examination	118	23.7	37.3*	18.6	17.8	2.5
A patient/family interview	121	46.3	43.0*	6.6	3.3	0.8
3. Potential patient risk factors:						
Substance use or abuse	147	31.3	44.2*	16.3	6.8	1.4
Pt history of intraop awareness	146	45.2	31.5*	11.0	11.6	0.7
Limited hemodynamic reserve	145	46.3	38.6*	6.9	6.9	1.4
ASA status of 4 or 5	145	33.1	40.7*	11.0	13.1	2.1
4. Procedures/ anesthetic techniques that may place a patient at risk for intraop awareness:						
Cesarean section under GA, cardiac surgery, trauma, emergency surgery	151	70.2*	27.2	0.7	1.3	0.7
Planned use of reduced doses of anesthetics in the presence of paralysis	148	48.6	44.6*	4.1	2.7	0.0
Planned use of muscle relaxants for maintenance	147	21.1	34.7*	16.3	26.5	1.4
Planned use of total intravenous anesthesia	146	13.0	26.7	24.0*	32.2	4.1
Planned use of volatile anesthetics	148	0.7	10.1	10.1	63.5*	15.5
Planned use of nitrous oxide-narcotic anesthesia	147	11.6	46.9*	18.4	19.7	3.4
Preoperative or intraoperative use of beta-blockers under general anesthesia	148	4.7	31.1	23.0*	36.5	4.7
Rapid-sequence induction	148	3.4	31.1	18.9*	41.9	4.7
5. All pts should be informed of the possibility of intraop awareness	147	15.0	28.6	10.9*	40.1	5.4
6. Only patients considered to be at elevated risk of intraop awareness should be informed of the possibility of intraop awareness	112	17.0	49.1*	7.1	21.4	5.4

[†††] N = the number of members who responded to each item. An astrisk beside a percentage score indicates the median.

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	N	Strongly Agree	Agree	Uncertain	Disagree	Strongly Disagree
7. Informing the pt preoperatively of the risk of intraop awareness increases the *actual* risk of intraoperative awareness	147	2.7	10.9	33.3	38.8*	14.3
Preinduction activities:						
8. The functioning of anesthesia delivery systems should be checked preoperatively to reduce the risk of intraop awareness	148	60.8*	37.8	0.7	0.7	0.0
9. A benzodiazepine or scopolamine should be used as a component of the anesthetic to reduce the risk of intraop awareness:						
For all patients under GA	150	15.3	34.0	6.0*	30.7	14.0
For no patients under GA	144	0.7	2.8	3.5	50.7*	42.4
For pts with conditions that may place them at risk for intraop awareness	148	37.8	56.1*	3.4	2.7	0.0
For patients requiring smaller dosages of general anesthetics (“light anesthesia”)	150	31.3	60.7*	4.7	3.3	0.0
For patients undergoing cardiac surgery	147	39.5	48.3*	9.5	2.7	0.0
For patients undergoing Cesarean section under GA	151	13.2	23.2	27.8*	28.5	7.3
For patients undergoing emergency surgery under GA	151	21.1	42.4*	21.9	13.9	0.7
For patients undergoing trauma surgery under GA	150	24.0	44.7*	22.7	8.7	0.0
For patients undergoing total intravenous anesthesia	150	23.3	48.0*	14.0	12.7	2.0
Intraoperative Monitoring:						
10. Commonly used clinical techniques (e.g., checking for purposeful or reflex movement) are valuable and should be used to detect intraop consciousness	151	10.6	50.3*	21.2	13.9	4.0
11. Conventional monitoring systems are valuable and should be used to detect intraoperative consciousness	150	20.7	56.7*	9.3	10.7	2.7

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	N	Strongly Agree	Agree	Uncertain	Disagree	Strongly Disagree
12. Brain function monitors are valuable and should be used to reduce the risk of intraoperative awareness:						
For all patients under GA	149	10.7	10.7	16.1	37.6*	24.8
For no patients under GA	146	2.7	3.4	24.7	44.5*	24.7
For pts with conditions that may place them at risk for intraop awareness	147	21.1	48.3*	19.0	10.2	1.4
For patients requiring smaller dosages of general anesthetics (“light anesthesia”)	147	19.7	38.8*	24.5	13.6	3.4
For patients undergoing cardiac surgery	148	20.3	33.8*	30.4	12.2	3.4
For patients undergoing Cesarean section under GA	148	12.8	34.5	25.0*	23.0	4.7
For patients undergoing emergency surgery under GA	146	17.8	26.0	28.8*	24.0	3.4
For patients undergoing trauma surgery under GA	148	18.9	29.7	28.4*	19.6	3.4
For patients undergoing total intravenous anesthesia	148	13.5	35.1	25.7*	20.3	5.4
13. Brain function monitors are valuable and should be used when possible to assess intraoperative depth of anesthesia:						
For all patients under GA	150	12.0	9.3	16.0	30.7*	32.0
For no patients under GA	147	2.7	4.8	24.5	41.5*	26.5
For pts with conditions that may place them at risk for intraop awareness	148	20.3	43.2*	20.9	10.8	4.7
For patients requiring smaller dosages of general anesthetics (“light anesthesia”)	149	20.1	37.6*	20.8	15.4	6.0
For patients undergoing cardiac surgery	149	20.1	27.5	28.2*	19.5	4.7
For patients undergoing Cesarean section under GA	149	13.4	30.2	22.8*	26.2	7.4
For patients undergoing emergency surgery under GA	149	14.8	26.8	24.8*	26.8	5.4
For patients undergoing trauma surgery under GA	149	16.1	28.9	25.5*	24.2	5.4
For patients undergoing total intravenous anesthesia	149	15.4	32.9	24.8*	20.1	6.7

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	N	Strongly Agree	Agree	Uncertain	Disagree	Strongly Disagree
Intraoperative & Postoperative Interventions:						
14. Benzodiazepines or scopolamine should be administered intraoperatively to prevent awareness after a pt has unexpectedly become conscious	151	33.1	49.7*	9.9	7.3	0.0
15. Once an episode of intraoperative awareness has been reported, a structured interview should be conducted to define the nature of the episode	151	49.0	43.0*	7.3	0.7	0.0
16. Once an episode of intraop awareness has been reported, a questionnaire should be given to define the nature of the episode	151	19.9	21.9	38.4*	18.5	1.3
17. Once an episode of intraop awareness has been reported and documented, the pt should be offered counseling or psychological support	151	44.4	39.1*	14.6	1.3	0.7
18. Once an episode of intraop awareness has been reported, an occurrence report concerning the event should be completed for the purpose of quality management	151	47.7	41.1*	9.3	1.3	0.7

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Exhibit 110: Letter from James L. Hall to Alberta Phillips, Jan. 2, 2004

TEXAS DEPARTMENT OF CRIMINAL JUSTICE

Gary Johnson
Executive Director

Carl Reynolds
General Counsel

January 2, 2004

Ms. Alberta Phillips
Austin American-Statesman
Editorial Department
305 South Congress Ave.
Austin, Texas 78704

Re: Request for Information Dated December 12, 2003

Dear Ms. Phillips:

This responds to your requests dated December 9, 2003 and December 12, 2003 (except the second part of item # 1 of your December 12, 2003 request) for information relating to the execution procedures for persons sentenced to death in Texas. That part of item #1 will be addressed via separate correspondence.

Information about execution procedures is held in the strictest of confidence, is generally not reduced to writing, and is known to only a few people within the Department. That confidentiality is maintained to assure that security procedures established for executions are not compromised. Thus, to the extent that we have written policies and procedures responsive to your request, that information has been found to be confidential and not available to the public. See OR 2001-2850 dated July 2, 2001 and OR 2003-1091 dated February 19, 2003. Because the information found to be excepted from release by the above noted opinions is exactly the same information responsive to much of your requests, we decline to make it available to you pursuant to Govt. Code §552.301(a). The Attorney General has made it quite clear that a governmental body need not request a decision if there has been a previous determination that the requested material falls within one of the exceptions to disclosure. See ORD 673 (2001); ORD 665 (2000).

Responding to other items of your requests not covered above, it is my understanding that the TDCJ Public Information Officer has already provided to you information regarding the dosages of the three chemicals used in lethal injections. Also, with regard to drugs used in the execution process and policies about handling those substances, the Department holds a DEA controlled substances registration certificate. See the applicable federal regulations with regard to policies about handling those controlled substances. (Title 21, Code of Federal Regulations 1300 *et seq.).* We have no information to indicate missing, misplaced or stolen drugs used in the execution

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process. Neither autopsies nor toxicology tests are performed on executed inmates since execution is carried out pursuant to order of the court. We have no information on "botched" executions.

With regard to your questions about policies for handling of controlled substances and missing, misplaced or stolen drugs, assuming your questions relate to drugs used in the execution process, we have no responsive written policies, but are vigilant in ensuring proper and secure storage and replacement prior to expiration date as set out in the above noted federal regulations.

Finally, we have no written information responsive to your request other than that noted above. I would point out that the only other responsive information of which we are aware is found in the Code of Criminal Procedure, Article 43.14, *et seq.*

Sincerely,

James L. Hall
Assistant General Counsel
OFFICE OF THE GENERAL COUNSEL

c: Carl Reynolds
General Counsel

JLH/kjb
020104006JH/OR/Phillips

Exhibit 111: ***Defendants' Supplemental Response in Opposition to Request for Expedited Discovery,*** **Aldrich v. Johnson, No. 04-2955 (S.D. Tex. 2004)**

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

DONALD LOREN ALDRICH, **Plaintiff**	§	
v.	§	
GARY JOHNSON, Executive Director, Texas Department of Criminal Justice	§	Civil Action No. 04-2955
	§	U.S. District Judge David Hittner
DOUG DRETKE, Director, Texas Department of Criminal Justice, Correctional Institutions Division	§	*** DEATH PENALTY CASE ***
JOE FERNALD, Senior Warden, Huntsville Unit Huntsville, Texas,	§	
and	§	
UNKNOWN EXECUTIONERS, **Defendants.**	§	

DEFENDANTS' SUPPLEMENTAL RESPONSE
IN OPPOSITION TO REQUEST FOR EXPEDITED DISCOVERY

Defendants ("the Prison") oppose death row prisoner Donald Aldrich's latest requests for "emergency status conference," injunctive relief, and expedited discovery regarding his belated contention that the substances used in Texas' lethal injection method of execution will cause foreseeable torture and a lingering death, in violation of the Eighth Amendment's Cruel and Unusual Punishments Clause. The Prison filed

a formal opposition last week, and now supplements that response to inform the Court about *Reid v. Johnson*, a method-of-execution federal court case that was decided about two weeks ago. *See Reid v. Johnson*, No. 3:03CV1039, 2004 WL 2022900 (E.D.Va. Sept. 3, 2004) (attached hereto as Exhibit A). Citing to *Nelson, Gomez, and Harris, Reid* essentially holds that death row prisoners facing execution by lethal injection have no viable Eighth Amendment claim for relief on the merits or otherwise. In addition to the arguments the Prison has already given as to why Aldrich's requests for injunctive relief and expedited discovery should be denied, and in an attempt to more closely comply with the Court's September 15, 2004 written order directing the Prison to quickly respond to Aldrich's specific request for expedited discovery, the Prison explicitly opposes such discovery for the reasons that follow, urges this Court to take judicial notice of the findings and thorough reasoning set forth in *Reid*, and again asks that Aldrich's challenge be dismissed in its entirety. Aldrich simply cannot overcomes the procedural bars that prohibit this Court from considering the merits of his new complaints. Nor can he establish a prima facie Eighth Amendment claim for relief based on discomfort he might experience during his execution. *See* Rules Governing § 2254 Cases, Rule 6(a), 28 U.S.C.A. foll. § 2254.

I.

Aldrich has offered considerable speculation, conjecture, and skepticism about the level of pain he may experience during his execution. But without a strong showing from him that Texas's lethal injection method of execution is cruel and unusual punishment under the Eighth Amendment, there is no good reason to grant his discovery request for "numerous documents concerning Texas' execution method, protocols, . . . procedures, and post-mortem reports of executed inmates." *See* Order dated September 16, 2004. Aldrich has not made the necessary showing.

The pertinent aspects of Texas's lethal injection method of execution are already a matter of public record. The process provides for three chemical agents to be administered as follows: first, two needles (one is a back-up) are inserted into each arm of the condemned inmate and connected to several intravenous drip bags containing a saline solution. Next, a lethal dose (3 grams) of sodium thiopental is given to sedate the inmate. Then, the intravenous tube is flushed with saline solution. Next, pancuronium bromide (20 milligrams) is administered to collapse the offender's diaphragm and lungs. The intravenous tube is flushed again with saline solution. And finally, potassium chloride (70 milliliters) is administered to stop the offender's heart. Death results from anesthetic overdose and respiratory and cardiac arrest. *See* Lise Olsen, *'Stakes are High' in Death Appeals*, HOUS. CHRON., Dec. 12, 2003, 2003

WL 68828246 (citing Texas Department of Criminal Justice, Death Penalty Information Center).

Texas's procedure is similar to that used in Virginia, and which a federal district court upheld as constitutional earlier this month. *Reid*, 2004 WL 2022900, at * 2, 8-9. As *Reid* explains, "sodium thiopental is a barbiturate sedative. Two grams of sodium thiopental is approximately five to eight times the dosage that would be used to render a 176 pound individual unconscious for general surgery." *Id.* at *2. Texas administers ***three*** grams. *See* Lise Olsen, *'Stakes are High' in Death Appeals*, HOUS. CHRON., Dec. 12, 2003, *available at* 2003 WL 68828246. The high level of barbiturate renders the inmate unconscious within moments, with only the remotest possibility of an awakening while the next two drugs are given. *See Ex parte Granviel,* 561 S.W.2d 503, 508 (Tex. Crim. App. 1978) (en banc) (rejecting petitioner's challenge to the State's use of sodium thiopental); *Reid*, 2004 WL 2022900, at * 2. *Reid* explains this reality very clearly:

> The probability of the inmate regaining consciousness within the ensuing ten minutes is 3/1000 of one percent. The probability of the inmate regaining consciousness by minute fifteen is 6/1000 of one percent. The probability of the inmate regaining consciousness within twenty minutes never rises above 1/100 of one percent. In light of the inordinately high dosage [of barbiturate], the weight or other physical attributes peculiar to a particular inmate will have a negligible impact on these probabilities. Flushing of the IV line prevents the sodium

> thiopental and the second and third drugs from interacting outside of the body of the inmate.
> . . . In light of the large dose of sodium thiopental, the inmate does not experience any pain associated with any potential involuntary motor reactions [caused by the next drug, pancuronium bromide].

Id. at *2-3.

This Court should not be persuaded by Aldrich's suggestion that he may re-awaken during the execution process. *See* Aldrich's Memorandum of Law in Support of Complaint at 3-4. The large does of sodium thiopental "assures the inmate's unconsciousness." *Reid*, 2004 WL 2022900, at * 3. Further, "[b]etween each step, the IV line is flushed with a syringe. The flushing procedure ensures that each of the chemicals reaches the body in the dosage and order in which they are administered." *Reid*, 2004 WL 2022900, at *2. Moreover, the "chemical properties of sodium thiopental and the extreme dose administered dispel the suggestion that contact between pancuronium [bromide] and sodium thiopental in the IV line would significantly hinder the effectiveness of the sodium thiopental." *Id.* at *2, n. 9. Hence, it is not at all "probable" that the sedative will be "ineffective or neutralized.". *See* Aldrich's Memorandum of Law in Support of Complaint at 5-6; *Reid*, 2004 WL 2022900, at *2.

Supposed "heightened" concerns about "lack of medical personnel, the lack of proper monitoring of the inmate during the process and the lack of inmate-specific

dosing of the barbiturate" may also be swiftly dispelled. *See* Aldrich's Memorandum of Law in Support of Complaint at 4, 8-11. The three grams of barbiturate in the first step of the execution process is an "inordinately high dosage," so the "weight or other physical attributes peculiar to a particular inmate will have [only] a negligible impact" on the infinitely small likelihood that the inmate might regain consciousness. *Reid*, 2004 WL 2022900, at *2.

Further, any harm that may be "attributable not to the drugs to be administered but . . . to the remote possibility of human error" is particularly speculative and entirely irrelevant as to whether the Prison should be enjoined from administering the particular recipe of chemicals they plan to use to execute Aldrich by lethal injection. *Id.* at *6. "The possibility that there may be some minor difficulty locating a vein does not subject [the inmate] to the offensive punishments the Eighth Amendment prohibits." *Id.* Moreover, the quantities and sequence of the lethal injection chemical cocktail are not arbitrary, capricious, malicious or unjustifiable. Essentially the same chemical formula has been debated and overwhelmingly adopted by every United States legislature or penal system that utilizes lethal injection as the method of execution. *See also Reid*, 2004 WL 2022900, at *2-3 (discussing the rationale behind Virginia's corresponding administration of sodium thiopental, pancuronium bromide, and potassium chloride, and rejecting suggested alternatives).

Speculation about the harm Aldrich may suffer due to the lack of physician involvement in the execution process also fails to establish that the lethal injection method of execution violates the Eighth Amendment. *Id.* at *7. As *Reid* observes, complaints about the Prison's personnel and training are habeas claims—and "outside the boundaries of § 1983"—because they are "tantamount to a challenge to lethal injection generally." *Id.* at *4. And, as of this writing, this Court is still without jurisdiction to consider the merits of those particular claims. 28 U.S.C. § 2254(b)(3)(A). *See, e.g., United States v. Key*, 205 F.3d 773, 774 (5th Cir. 2000).

Lastly, Aldrich's request for post-mortem reports of executed inmates should also be denied. Such reports will not add credibility or factual support to his claim that the three-part lethal injection chemical mixture will cause a tortuous death. As *Reid* explains, post-mortem toxicology reports cannot establish whether an executed inmate awoke after being given the heavy initial dose of sedative:

> The lack of pertinent information regarding when and how the blood was gathered renders these reports of little value as a basis for rendering an opinion based on reasonable medical certainty as to the amount of sodium thiopental that had actually reached the inmate's system. . . . [T]he sodium thiopental level found in the toxicology report for a particular inmate is not indicative of the consciousness of that inmate during his execution . . .

Reid, 2004 WL 2022900, at * 3.

Aldrich's request for expedited discovery should be denied. His challenge to the execution process is without merit.

II.

The Prison also reiterates that dismissal is the most appropriate course of action at this point given the procedural bars that exist in this case. First, having chosen to file a lawsuit in this Court before complaining directly to the Prison about its lethal injection procedures, Aldrich has neglected to exhaust his administrative remedies. *See* 42 U.S.C. § 1997e(a) (requiring prisoners who seek to bring a § 1983 suit against the Prison to first exhaust available administrative remedies). Second, Aldrich's broad request for relief warrants a finding that this lawsuit is an unauthorized successive federal habeas application. Though there is no foreseeable probability that Aldrich's execution will involve "torture or a lingering death," it was entirely foreseeable at the time Aldrich committed capital murder in 1993 that, if convicted, he would be assessed a penalty of death by lethal injection. Aldrich was convicted, and he has been residing on Texas's death row for the last ten years. His delay in bringing this latest challenge should not be rewarded by a grant of "expedited discovery"—or discovery of any kind—three weeks before his long-awaited scheduled execution.

Respectfully submitted,

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First Assistant Attorney General

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Deputy Attorney General
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ATTORNEYS FOR DEFENDANTS

CERTIFICATE OF SERVICE

I, Carla Eldred, Assistant Attorney General of Texas, certify that a copy of this, **Defendants' Supplemental Response In Opposition to Request for Expedited Discovery**, was served by facsimile transmission to (713) 743-2131 *and* by overnight mail on September 20, 2004, addressed to Plaintiff's counsel:

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Carla Eldred

CARLA ELDRED
Assistant Attorney General

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION.

DONALD LOREN ALDRICH, **Plaintiff**	§	
v.	§	
GARY JOHNSON, Executive Director, Texas Department of Criminal Justice	§	Civil Action No. 04-2955
	§	U.S. District Judge David Hittner
DOUG DRETKE, Director, Texas Department of Criminal Justice, Correctional Institutions Division	§	
	§	*** DEATH PENALTY CASE ***
JOE FERNALD, Senior Warden, Huntsville Unit Huntsville, Texas	§	
and	§	
UNKNOWN EXECUTIONERS, **Defendants.**	§	

ORDER

Plaintiff's request for expedited discovery is DENIED.

So ordered this ___ day of _____, _____.

_____
DAVID HITTNER
U.S. DISTRICT COURT JUDGE

Exhibit 112: Lisa Olsen and Mike Tolson, "Stakes are High in Death Appeals, HOU. CHRON., Dec. 12, 2003, at A1

'Stakes are high' in death appeals ;Court may see civil rights

The Houston Chronicle

December 12, 2003, Friday 2 STAR EDITION

SECTION: A; Pg. 1

LENGTH: 1222 words

HEADLINE: 'Stakes are high' in death appeals ;
Court may see civil rights issue

SOURCE: Staff

BYLINE: LISE OLSEN, MIKE TOLSON

BODY:

U.S. Supreme Court Justice Antonin Scalia's decision to halt the execution of a Texas inmate Wednesday could open the door for similar delays in early 2004 and even lead to a re-examination of the constitutionality of the method of lethal injection.

Or, depending on what the court does next, it could have virtually no impact.

The stay that spared Kevin Lee Zimmerman, 42, from the needle on Wednesday came less than two weeks after the Supreme Court had agreed to hear an Alabama case that also challenges lethal injection.

Lawyers for Zimmerman said they hope his stay signals the court's interest in the underlying issue of whether the drugs used to bring about death in Texas amount to cruel and unusual punishment.

However, the court is more likely to consider an overarching legal issue: the precise way in which challenges to lethal injection can be considered as violations of inmates' civil rights by federal courts.

"I would be surprised if the Supreme Court was reaching out to answer the lethal injection question," said Jordan Steiker, a University of Texas law professor and capital punishment expert. "This is not an issue that has been addressed in many jurisdictions. What has blocked it in many circuits is a threshold, procedural question."

The question, Steiker said, is something the court may want to address: Should a claim made by a defendant that amounts to a civil rights issue be considered as part of his normal federal appeals, or can his attorney pursue a separate appeal under an established provision of civil rights law?

"The stakes are high because of the types of claims that can be brought," Steiker said.

Since lethal injection is used in nearly all U.S. executions, dozens of other death row inmates will probably try to seek stays in 2004 as the court considers the Alabama case - and perhaps the one in Texas.

"There's certainly been a lot of interest in this from lawyers around the country, and everyone's watching to see what's going to happen," said Jim Marcus, executive director of the Texas Defender Service and the lead counsel in Zimmerman's appeal.

In the Texas case, originally filed as a civil rights claim in a Houston federal court, lawyers allege that the three-drug combination used in lethal injections could cause suffering and pain that the inmate would be unable to express because the second drug in the sequence causes paralysis. That type of drug was judged unacceptable by the American Veterinary Medical Association for the euthanasia of animals.

Texas has used the same three drugs since about 1982, prison officials said.

The Alabama case is different, though both appeals argue that lethal injection is cruel. In that case, an inmate who was a drug addict has argued that prison workers who are not medically trained will have to cut deep into his arms to find veins to execute him.

In both the Alabama and Texas cases, lawyers for the inmates originally tried to present their argument as civil rights violations, but were rejected by lower federal courts.

The 5th U.S. Circuit Court of Appeals has held that civil rights claims must be considered along with a defendant's normal habeas corpus appeal. If such claims were considered separately, it would be easier to get them fully aired, Steiker said.

One of Zimmerman's attorneys, David Dow, believes the Supreme Court likely wants to do more than resolve a procedural conflict.

"The fact that it stopped the Texas case means the underlying issue is intriguing to the court," Dow said. "It would be unusual to consider the procedural issue if they did not think that the underlying issue had some merit."

Zimmerman was the second condemned Texas prisoner this week to escape death because of the same appeal, at least temporarily. On Tuesday, the scheduled execution of Billy Frank Vickers, 58, was called off at midnight when the 5th Circuit refused to rule on the case, which was filed on behalf of Zimmerman, Vickers and a third man. Vickers' death warrant expired.

Dow and Steiker agreed Zimmerman's stay could have been prompted by events of the day before, when the 5th Circuit failed to act on the case before Vickers' scheduled execution. The court's inaction prompted prison officials, supported by the state attorney general's office, to essentially disobey a court order calling for Vickers' execution.

"It would certainly appear problematic for an execution to go forward without the imprimatur of the federal court," Steiker said. "It would have made the state of Texas look bad to act in the vacuum of authority, but would have made the 5th Circuit look worse."

Dow wonders whether the Supreme Court has finally lost faith in the 5th Circuit's review of capital cases and is now inclined to give them closer scrutiny.

No further action was taken Thursday by the Supreme Court.

If Zimmerman's stay remains in effect, lawyers nationwide are expected to seek similar relief for clients.

"Clearly defense attorneys are going to file similar motions - they would be derelict in their duties if they did not," said Richard Dieter, executive director of the nonprofit Death Penalty Information Center.

About 15 executions are scheduled in the United States for 2004, and one is pending in Virginia this month. Lethal injection is used in 37 of the 38 death penalty states. Nebraska uses the electric chair.

CARRYING OUT THE DEATH PENALTY IN TEXAS

In 1977, Oklahoma became the first state to adopt lethal injection as a means of execution, though it would be five more years until Charles Brooks would become the first person executed by lethal injection in Texas on Dec. 7, 1982.

A total of 313 Texas inmates have been executed by injecting the same mixture of drugs over the past 21 years.

The drugs

Sodium thiopental Type: Fast-acting barbituate Dose: 3 grams (Comes in a kit containing one gram of powder and 50 milliliters of sterile water. Three kits are used.)

Pancuronium bromide Type: Neuromuscular blocking agent Dose: 20 milligrams (liquid form) Potassium chloride Type: A salt that, in much smaller doses, is used to treat potassium deficiency. Dose: 70 milliliters (liquid form)

The procedure

1 The condemned person is strapped to a gurney.

2 Two needles (one is a back-up) are inserted into usable veins in the inmate's arms.

3 Long tubes connect the needle through a square hole in the wall to several intravenous drip bags.

4 A harmless saline solution drip is started immediately.

5 A lethal dose of sodium thiopental is given to sedate the inmate. This takes about 30 seconds.

6 The intravenous tube is flushed with saline solution.

7 Pancuronium bromide is admin-istered to collapse the offender's diaphragm and lungs. The entire muscle system is paralyzed and the inmate's breathing stops. This takes about 45 seconds.

8 The intravenous tube is flushed again with saline solution.

9 Potassium chloride is administered to stop the offender's heart. This takes about 30 seconds.

10 Death results from anesthetic overdose and respiratory and cardiac arrest. Executions nationwide

Of the 38 states that have the death penalty, 37 use lethal injection.

U.S. executions since 1976:

718 Lethal injection 151 Electrocution 11 Gas chamber 3 Hanging 2 Firing squad 885 TOTAL

GRAPHIC: Graph: 1. CARRYING OUT THE DEATH PENALTY IN TEXAS (TEXT, p. 21); Photo: 2. Behind the mirrored window in the Huntsville death chamber is where lethal injections are mixed. (p. 21); 1. B.C. Oren / Chronicle, Source: Texas Department of Criminal Justice, Death Penalty Information Center, 2. E. Joseph Deering / Chronicle

LOAD-DATE: October 15, 2004

Exhibit 113: TDCJ Response to Complaint of Charles Daniel Thacker

Exhibit 114: Declaration of Dr. Mark Heath, filed in Oken v. Sizer, et. al., No. 24-C-004242, (Cir. Ct. Balt. City 2004)

IN THE
CIRCUIT COURT FOR
BALTIMORE CITY, MARYLAND

Steven Howard Oken,

Plaintiffs,

v.

Frank C. Sizer, Jr., Commissioner
Maryland Division of Correction,

William Williams, Warden
Maryland Correctional Adjustment Center,

Gary Hornbaker, Warden
Metropolitan Transition Center,

and

Unknown Executioners,

Defendants.

AFFIDAVIT OF MARK J. S. HEATH, M.D.,
BOARD CERTIFIED ANESTHESIOLOGIST

I, Mark J. S. Heath, after being duly sworn and cautioned, hereby affirm as follows:

1. My name is Mark J. S. Heath, M.D., I am an Assistant Professor of Clinical Anesthesiology in the Department of Anesthesiology at Columbia University in New York City, N.Y. I received my Medical Doctorate degree from the University of North Carolina at Chapel Hill in 1986 and completed residency and fellowship training in Anesthesiology in 1992 at Columbia University Medical Center. I am Board Certified in Anesthesiology, and am licensed to practice Medicine in New York State. My work consists of approximately equal parts of performing clinical anesthesiology, teaching residents, fellows and medical students, and directing a neuroscience laboratory. As a result of my training and research I am familiar and proficient with the use and pharmacology of the chemicals used to perform lethal injection.

2. Over the past several years, as a result of concerns about the mechanics of lethal injection as practiced in the United States, I have performed several hundred hours of research into the techniques that are used during this procedure. I have been admitted as an expert medical witness in courts in Georgia, Tennessee, Pennsylvania, and Louisiana. I have filed affidavits that have been reviewed by courts in the above states and have also submitted

affidavits in courts in South Carolina, Texas, Virginia, Oklahoma, New York, Alabama, North Carolina, California, Ohio, and in the United States Supreme Court. During court proceedings I have heard testimony from prison wardens who are responsible for conducting executions by lethal injection. I have testified before the Nebraska Senate Judiciary Committee regarding proposed legislation to adopt lethal injection. My research regarding lethal injection has involved both extensive conversations with recognized experts in the field and personal correspondence with the individuals responsible for introducing lethal injection as a method of execution in Oklahoma and the United States.

3. My qualifications are further detailed in my curriculum vitae, a copy of which is attached hereto as Exhibit A and incorporated by reference as if fully rewritten herein.

4. I have reviewed the state of Maryland's Department of Public Safety and Correctional Services Division of Correction, Division of Correction Manual 110-2 Execution Procedures (hereinafter Execution Procedures) Revised 4/1/94, which is attached to this affidavit, a copy of Md. Code Correctional Services Article Section 3-905 Method of Execution, a copy of Md. Code Criminal Law, Section 10-611, an affidavit from a witness during the lethal injection of Tyronne X Gilliam and my own interviews of another witness present at that execution on November 16, 1998.

5. The information contained in the Execution Procedures and other materials listed above raise the following concerns about Maryland's lethal injection procedure. These concerns arise both from the details disclosed in the above documents and from medically relevant, logical inferences drawn from the omission of details in the documents (*e.g.*, details regarding the training of the personnel involved; and details of the precise methods by which the personnel involved use the equipment to carry out an execution by lethal injection).

6. Maryland's Execution Procedures state that as part of its protocol for lethal injection, Maryland uses the drugs sodium thiopental (also know as "thiopental " and "pentothal"), pancuronium bromide (also know as "pancuronium" and "Pavulon"), and potassium chloride (also known as "KCl").

7. Initially, I would note that the Maryland General Assembly specified the Department of Corrections to utilize two drugs in judicial lethal injection executions, an ultrashort acting barbiturate which was to be continuously administered in conjunction with a paralytic agent. The Execution Procedures, however, reveal that the Department of Corrections specifies the use of a third drug, potassium chloride and fails to continuously administer the ultra short acting barbiturate as directed in the statute. These discrepancies are significant for several important reasons.

8. In order for the State of Maryland to achieve a humane death, it is essential that the pentothal succeeds in rendering the inmate unconscious. If for any reason the pentothal fails to render and maintain unconsciousness, the inmate will experience conscious paralysis due to pancuronium. Conscious paralysis is a terrifying experience in which the inmate would suffer

the agony of suffocation, amplified by the terror of being unable to struggle in any way. Further, if the dose of pentothal fails to render and maintain unconsciousness, the inmate will experience the agony of the injection of concentrated potassium. Concentrated potassium, when injected into a vein, causes an excruciating burning pain. This pain would extend from the site of the injection all the way to the heart. To summarize, failure of the pentothal to render and maintain a state of unconsciousness would result in the inmate experiencing suffocation, paralysis, terror, and agonizing pain.

9. Sodium thiopental is an ultrashort-acting barbiturate that if administered in inadequate dosage begins to wear off almost immediately.

10. Sodium thiopental has a short shelf life in liquid form. Thiopental is distributed in powder form to increase its shelf life; it must be mixed into a liquid solution by trained personnel before it can be injected. Thus, an improper preparation of the solid form into the liquid form or letting the chemical sit for too long will prevent the chemical from having its normal effect of rendering the inmate unconscious.

11. When anesthesiologists use sodium thiopental, we do so for the purposes of temporarily anesthetizing patients for sufficient time to incubate the trachea and institute mechanical support of ventilation and respiration. Once this has been achieved, additional drugs are administered to maintain a "surgical depth" or "surgical plane" of anesthesia (*i.e.*, a level of anesthesia deep enough to ensure that a surgical patient feels no pain and is unconscious for the duration of the surgical procedure). The medical utility of thiopental derives from its ultrashort-acting properties: if unanticipated obstacles hinder or prevent successful incubation, patients will quickly regain consciousness and will resume ventilation and respiration on their own.

12. Sodium Thiopental is not used to maintain a patient in a surgical plane of anesthesia for purposes of performing surgical procedures. It is unnecessary, and risky, to use a short-acting anesthesia in the execution procedure. If the solution of sodium thiopental comes into contact with another chemical, such as pancuronium bromide, the mixture of the two will cause the sodium thiopental immediately to crystallize. These factors are significant in the risk of the inmate not being properly anesthetized, especially since no-one checks that the inmate is unconscious before the second drug is administered.

13. The benefits of thiopental in the operating room engender serious risks in the execution chamber. Based on the information I have available to me concerning Maryland's execution protocol, a two (2) gram dose of sodium thiopental is apparently administered in a single injection from a single syringe. By contrast, based on my research and the research of others into the procedures for executing human beings by means of lethal injection, the original design of the lethal injection protocol called for the **continuous** intravenous administration of an ultrashort-acting barbiturate. Based on my research and the research of others, the central elements of the lethal-injection procedure used in Maryland is similar to the one adopted many years ago in Oklahoma (which, it appears, many states used as a model without substantive independent research). Oklahoma requires the "continuous intravenous administration of an ultrashort-acting barbiturate" (Oklahoma Statutes, Title 22 Criminal Procedure, Chapter 17 part

1014 A).

14. The use of a continuous administration of the ultrashort-acting barbiturate is essential to ensure continued and sustained unconsciousness during the administration of pancuronium and potassium chloride. I have reviewed Md. Code, Correctional Services section 3-905, *Methods of Execution*. This statute mandates a "continuous intravenous administration of a lethal quantity of an ultrashort-acting barbiturate." However, the Department of Corrections Execution Procedures explicitly state otherwise. Therefore, it does not appear that Maryland follows its own "continuous" requirement as mandated by statute. It is my opinion based on a reasonable degree of medical certainty that, given that the Department of Corrections has selected an ultrashort-acting barbiturate, this failure to require a continuous infusion of thiopental places the condemned inmate at a needless and significant risk for the conscious experience of paralysis during the excruciating pain of both suffocation and the intravenous injection of potassium chloride.

15. Based on my research into lethal injection, the dose of pentothal described in the Maryland protocol, 2 grams, is considerably lower than the doses described in the protocols of many states and the Federal Government. It is my opinion based on a reasonable degree of medical certainty that Maryland's relatively low dose of thiopental amplifies the concern relating to the single injection (as opposed to continuous infusion) of this ultrashort-acting barbiturate, thereby further elevating the risk that the condemned person will suffer excruciating pain masked by the pancuronium.

16. As with most drugs, a person's body composition and physiological attributes (size, weight, and drug tolerance) causes the inmate to react differently to the chemicals. Thus, some prisoners may need a higher concentration of sodium thiopental than others before losing consciousness. Maryland's failure to account for each inmate's physiological composition creates a significant probability that the inmate will not be unconscious when the other chemicals are administered causing the inmate to suffer an excruciatingly painful death.

17. If sodium thiopental mixes with pancuronium bromide in the intravenous tubing, it will precipitate out of solution and be inactivated; this amplifies the risk that the inmate will receive an inadequate dose of sodium thiopental and enhances the risk that the inmate will be conscious during the execution.

18. The method of administering thiopental also raises significant concerns. If thiopental is not properly administered in a dose sufficient to cause death or at least the loss of consciousness for the duration of the execution procedure, then it is my opinion held to a reasonable degree of medical certainty that the use of pancuronium places the condemned inmate at risk for consciously experiencing paralysis, suffocation, and the excruciating pain of the intravenous injection of high dose potassium chloride.

19. Based on the information available to me, it is my opinion held to a reasonable degree of medical certainty that Maryland's lethal injection protocol creates an unacceptable risk that the inmate will not be anesthetized to the point of being unconscious and unaware of pain

for the duration of the execution procedure. If the inmate is not first successfully anesthetized, then it is my opinion to a reasonable degree of medical certainty that the pancuronium will paralyze all voluntary muscles and mask external, physical indications of the excruciating pain being experienced by the inmate during the process of suffocating (caused by the pancuronium) and having a cardiac arrest (caused by the potassium chloride).

20. Another major concern about the protocol relates to the use of the drug pancuronium bromide. Pancuronium paralyzes all voluntary muscles, but does not affect sensation, consciousness, cognition, or the ability to feel pain and suffocation. If the thiopental and potassium are to be given in doses sufficient to cause death, then it is my opinion held to a reasonable degree of medical certainty (and it is also a matter of common sense) that there would be no rational or medically justifiable place in the protocol for the use of pancuronium or any other chemical paralytic agent.

21. If administered alone, a lethal dose of pancuronium would not immediately cause a condemned inmate to lose consciousness. It first would totally immobilize the inmate by paralyzing all voluntary muscles and the diaphragm, causing the inmate to suffocate to death while experiencing an intense, conscious desire to inhale. Ultimately, consciousness would be lost, but it would not be lost as an immediate and direct result of the pancuronium. Rather, the loss of consciousness would be due to suffocation, and would be preceded by the torment and agony caused by suffocation. Depending on the physiological attributes of the individual it may take from one to several minutes before suffocation leads to unconsciousness.

22. It is my understanding that Maryland's execution protocol requires the presence of media witnesses to the execution, and permits the presence of witness chosen by the inmate and chosen by the victim's surviving family members. It is my opinion based on a reasonable degree of medical certainty that the use of pancuronium effectively nullifies the ability of witnesses to discern whether or not the condemned prisoner is experiencing a peaceful or agonizing death. Regardless of the experience of the condemned prisoner, whether he or she is deeply unconscious or experiencing the excruciation of suffocation, paralysis, and potassium injection, he or she will appear to witnesses to be serene and peaceful due to the relaxation and immobilization of the facial and other skeletal muscles.

23. Based on my research into issues related to lethal execution, I know that there was a time when pancuronium was an acceptable drug for use by veterinarians in the euthanasia of household pets such as dogs and cats; but that the use of pancuronium is now prohibited by many veterinary guidelines in this and other countries for precisely the reasons outlined above. Veterinary standards forbid creating the risk that household pets would die while pancuronium masks the type of excruciating pain human beings are exposed to in Maryland's execution protocol. The use of pancuronium fails to comport with the evolving "standard of decency" regarding the ending of life in household pets. Maryland is one of many states that has banned the usage of curariform drugs such as pancuronium bromide in the euthanasia of animals. (Maryland Criminal Law Section 10-611 states that "a person may not kill or allow a dog or cat to be killed by use of: (1) a decompression chamber; (2) carbon monoxide gas; or (3) curariform drugs"). In my medical opinion, based on a reasonable degree of medical certainty, the use of

pancuronium in the lethal injection protocol for executing human beings violates standards of decency designed to prevent the infliction of excruciating pain and suffering on household pets. Because the physiological features of neuromuscular signal transmission are highly conserved among vertebrates such as dogs, cats, and humans, it is an accepted matter of medical and veterinary certainty that conscious paralysis and suffocation by curariform drugs such as pancuronium is inhumane for any of these species.

24. In the lethal injection process, pancuronium bromide makes the prisoner appear serene because of its paralytic effect on the muscles. The facial muscles cannot move or contract to show pain and suffering, and become relaxed and thereby generate an impression of tranquility. Pancuronium therefore confers a 'chemical veil' to the procedure. Because pancuronium bromide is an invisible chemical veil and not a physical veil like a blanket or hood that is easily identifiable, the use of this chemical in lethal injection deceives observers into believing they have witnessed a humane event.. Thus, visual monitoring by citizen witnesses, counsel for the inmate, medical and prison personnel is rendered meaningless, as these individuals are unable to make any determination as to whether the procedure is humane. This results in a situation wherein neither the citizens of the state, nor the court itself are provided with any accurate information that can be used to develop an assurance that the execution procedure produces a humane death.

25. If administered alone, without prior administration of an anesthetizing dose of pentothal or other anesthetic agent, a lethal dose of potassium chloride would not immediately cause a condemned inmate to lose consciousness. It would first cause excruciating pain as it traveled through the venous system to the heart, and, once it reached the heart, it would cause a painful cardiac arrest that would deprive the brain of oxygen and rather quickly (but not immediately) cause death. If pancuronium was administered prior to the potassium chloride, any visible signs of pain or agony caused by the potassium would be completely masked and undetectable to onlookers or witnesses.

26. The preparation and administration of intravenous drugs is a complex endeavor that requires training, experience, and proficiency. There are many steps involved in achieving the successful administration of the correct does of a drug, and there are many opportunities for problems to arise which can thwart the goal of successfully delivering the intended dose of a drug.

27. Opportunities for problems with the administration of drugs during lethal injection include, but may not be limited to the following:

a) errors in preparation: pentothal is delivered in powdered form and must be mixed into an aqueous solution prior to administration. This preparation requires the correct application of pharmaceutical knowledge and familiarity with terminology and abbreviations. Calculation are also required, particularly if the protocol requires the use of a concentration of drug that differs from that which is normally used;

b) error in labeling syringes;

c) error in selecting the correct syringe during the sequence of administration;

d) error in correctly injecting the drug into the intravenous line. If a "three-way stopcock" is used, the stopcock may be turned in the wrong direction, resulting in a retrograde injection of the drug into the IV fluid bag rather than the inmate. The design of three-way stopcocks is counterintuitive to many individuals and the error of retrograde injection is widespread in clinical practice. Even seasoned professionals are known to make this error, although it should be noted that if they do make this error they are situated within inches of the patient and IV apparatus and are immediately able to recognize and intervene and address the problem. If an injection port is used without a stopcock, the IV tubing must be pinched or kinked upstream from the injection site, otherwise a retrograde injection into the intravenous fluid bag is likely to occur. Many individuals are not aware of this requirement. If the drug is retrogradely injected into the IV fluid bag, it will be greatly diluted and would take a very long time to drip into the inmate. If this were to occur during the injection of pentothal it is highly unlikely that an anesthetic dose would be administered prior to the injection of pancuronium.

e) the IV tubing may leak. An "IV setup" consists of multiple components that are assembled by hand prior to use. If the personnel who are injecting the drugs are not at the bedside but are instead in a different room or part of the room, multiple IV extension sets need to be inserted between the inmate and the administration site. Any of these connections may loosen and leak. Indeed, as noted below, the materials and interviews conducted by me with respect to the execution of Tyrone X. Gilliam lead me to the opinion within a reasonable degree of certainty that just such a leak transpired during that execution which the Execution Commander and Executioners either failed to detect or failed to take any corrective action. In clinical practice, it is important to maintain visual surveillance of the full extent of IV tubing so that such leaks may be detected. The configuration of the death chamber and the relative position of the executioners and the inmate may hinder or preclude such surveillance, thereby causing a failure to detect a leak. Further, in many executions, it is customary to cover the inmate's body and extremities with a sheet; if the IV tubing runs under a sheet it is difficult or impossible to detect the leakage of drugs during injection. In particular, if the IV tubing were to be incorrectly inserted into the hub of the catheter, there would be leakage of the drug under the sheet and under the inmate's body that would not be detectable;

f) incorrect insertion of the catheter. If the catheter is not properly placed in a vein, the pentothal will enter the tissue surrounding the vein but will not be delivered to the central nervous system and will not render the inmate unconscious. This condition, known as infiltration, occurs with regularity in the clinical setting. Recognition of infiltration requires continued surveillance of the IV site during the injection, and that surveillance should be performed by the individual who is performing the injection so as to permit correlation between visual observation and tactile feedback from the plunger of the syringe;

g) migration of the catheter. Even if properly inserted, the catheter tip may move or migrate, so that at the time of injection, it is not within the vein. This would result in

infiltration, and therefore a failure to deliver the drug to the inmate's circulation and failure to render the inmate unconscious;

h) perforation or rupture or leakage of the vein. During the insertion of the catheter, the wall of the vein can be perforated or weakened, so that during the injection some or all of the drug leaves the vein and enters the surrounding tissue. The likelihood of this occurring is increased if too much pressure is applied to the plunger of the syringe during injection, because a high pressure injection results in a high velocity jet of drug in the vein that can penetrate or tear the vessel wall;

i) even without damage or perforation of the vein during insertion of the catheter, excessive pressure on the syringe plunger during injection can result in tearing, rupture, and leakage of the vein due to the high velocity jet that exits the tip of the catheter. Should this occur, the drug would not enter the circulation and would therefore fail to render the inmate unconscious;

j) securing the catheter. After insertion, catheters must be properly secured by the use of tape, adhesive material, or suture. Movement by the inmate, even if restrained by straps, or traction on the IV tubing may result in the dislodging of the catheter. If this were to occur under a sheet, it would not be detected, and the drug would not enter the inmate's circulation and would not render the inmate unconscious;

k) failure to properly administer flush solutions between injections of drugs. Paralytic agents such as pancuronium cause pentothal to precipitate out of solution on contact, thereby interfering with the delivery of the drug to the inmate and to the central nervous system;

l) failure to properly loosen or remove the tourniquet from the arm or leg after placement of the IV catheter will delay or inhibit the delivery of the drugs by the circulation to the central nervous system. This may cause a failure of the pentothal to render and maintain the inmate in a state of unconsciousness;

m) restraining straps may act as tourniquets and thereby impede or inhibit the deliver of drugs by the circulation to the central nervous system. This may cause a failure of the pentothal to render and maintain the inmate in a state of unconsciousness. Even if the IV is checked for "free flow" of the intravenous fluid prior to commencing injection, a small movement within the restraints on the part of the inmate could compress the vein and result in impaired delivery of the drugs.

28. Procedures related to and involving the administration of intravenous drugs should only be undertaken and performed by personnel possessing the requisite experience, training, credentials, and proficiency.

29. The protocol for Maryland lethal injections fails to adequately describe, define, and establish the qualifications of the personnel who will be responsible for the conduct of the lethal injection procedure. The procedures state that the "Execution Team members are

responsible for all operations, equipment, and sanitation related to the Death House." Further, the procedures refer to "two designated trained officers to operate the lethal injection chamber." But, the procedures make no reference to the training or medical knowledge of the execution team members, the "two designated trained officers," or the individuals who train the execution team members and the designated officers.

30. The failure of the Maryland Department of Corrections to provide any reasonable assurances about the qualifications of the personnel serves to compound the risk that one of the problems outlined above will occur. The absence of such detail raises critical questions about the degree to which condemned inmates risk suffering excruciating pain during the lethal injection procedure. It is my opinion based on a reasonable degree of medical certainty that the correct and safe management of intravenous drug and fluid administration requires a significant level of professional acumen, and can not be adequately performed by personnel lacking the requisite training and experience. The great majority of prison employees, EMTs, and physician's assistants are not trained in the use of ultrashort-acting barbiturates. Therefore, the failure of the Maryland Department of Corrections to provide any reasonable assurance about the qualifications of the personnel serves to compound the risk that the inmate will not receive a successful administration of the intended dose of pentothal, and therefore will be subjected to torture rather than a humane execution.

31. Past lethal injection procedures conducted by the Maryland Department of Corrections raise deep concerns about the adequacy of the lethal injection procedure and whether inmates have been successfully anesthetized with pentothal. Specifically, Maryland seems to have had a problem with the IV tube leaking. I have reviewed the affidavit of Jerome H. Nickerson, Jr., concerning his observations of Tyrone X. Gilliam's execution in Maryland on November 16, 1998. Mr. Nickerson reported observing "fluid running down the exterior surface of the IV line," which "continued throughout Mr. Gilliam's execution. By the time Mr. Gilliam was pronounced dead a puddle of liquid had formed on the floor of the lethal injection chamber immediately below where the IV line was located."

32. Mr. Nickerson also stated that a Department of Corrections official stated that "dripping fluid during a lethal injection execution was 'normal.'" Such leakage is by no means "normal" during a lethal injection and the fact that a member of the execution team claimed otherwise proves that the execution team neither is properly trained to carry out a lethal injection nor has any basic understanding of the lethal injection process.

33. In addition to reviewing the affidavit of Mr. Nickerson, I spoke by telephone with Mr. Greg Toppo. At the time of Mr. Gilliam's execution Mr. Toppo worked as an Associated Press Reporter, and in this capacity he attended and reported on the execution. Mr. Toppo related to me in detail the observations that he was able to make from the perspective of the witness viewing room. Mr. Toppo related to me his "vivid memory of watching clear fluid drip down and wondering "what the heck is going on?"". To Mr. Toppo the source of the leak appeared to be "where the needle went in" to the inmate's skin. Mr. Toppo observed the fluid collect in an enlarging puddle on the floor of the execution chamber.

34. Additionally, Mr. Toppo told me that after the execution a prison official was asked by Ms. Caitlyn Francke of the Baltimore Sun about the significance of the IV fluid dripping on the floor. Mr. Toppo told me that the prison official acknowledged that the dripping of IV fluid on the floor had occurred, and further stated something to the effect that this was "normal", "expected", "no surprise", or something that "happens all the time" (Mr. Toppo did not recall the exact words used, and said the phrasing could have been any of the above).

35. The leakage of intravenous fluid during the induction of general anesthesia is a critical event that requires immediate intervention. Failure to recognize and correct leaking IV fluid during the induction of general anesthesia is likely to result in the failure to successfully administer the intended quantities of some or all of the drugs in the induction sequence. The same consideration applies to lethal injection, and there is strong grounds for concern that due to the leakage of fluid observed and acknowledge in Mr. Gilliam's execution that Mr. Gilliam experienced a cruel death. It is highly likely, if not almost certain, that Mr. Gilliam received significantly lower doses of pentothal, pancuronium, and potassium chloride than the doses stipulated by the protocol. Because the dose of pancuronium is far in excess of that which is required to induce complete paralysis, it is very possible that Mr. Gilliam received a dose of pentothal that failed to produce or maintain unconsciousness during the time when he was paralyzed by pancuronium. It is important to recognize that, because of the paralytic effect of pancuronium, it is not possible to ascertain or determine whether he in fact did experience conscious paralysis.

36. According to Maryland's Execution Procedures, the drugs are administered in the following sequence: pentothal (thiopental) -2 grams, dissolved in the least amount of diluent possible attain complete, clear suspension; Pavulon (pancuronium bromide) – 50 milligrams per 50 cc; and, potassium chloride – 50 milliequivalents per 50 cc each for two syringes. However, the checklist that must be filled out prior to carrying out an execution specifies different concentrations of the chemicals. While this discrepancy has no impact on the problems and concerns with the chemicals utilized and the quantities administered, it exemplifies the concerns with carrying out lethal injection by improperly trained individuals. It also demonstrates a strong possibility that condemned inmates do not receive the quantity of chemicals specified in the protocol, and that errors in the carrying out of lethal injection are likely to occur. Additionally there, are other significant internal discrepancies within the Execution Procedures. Within subsection 3(h) "IV Set Up Procedures," the Execution Procedures specify two syringes containing 100 milliequivalents of potassium chloride, two syringes each containing 100 milligrams of pavulon. Yet, within the section entitled "Contents of Syringes," the Execution Procedures specify two syringes containing 50 milligrams of pavulon and two syringes containing 50 milliequivalents of potassium chloride. Such internally inconsistent instructions compounds the concerns noted above of untrained and unqualified personnel conducting lethal injection and heighten the risk that inmates do not receive the quantity of chemicals intended by the authors of the Execution Procedures.

37. Post-mortem blood levels of pentothal conducted on executed inmates demonstrate that other states have experienced significant difficulty in achieving the consistent and reliable administration of pentothal For example, South Carolina, like Maryland,

administers 2 grams of sodium thiopental. Yet, toxicology studies conducted on South Carolina inmates show a wide range of post-mortem thiopental levels. Moreover, some of the thiopental levels detected in South Carolina were at a level highly unlikely to produce unconsciousness. For example, I am familiar with computer modeling suggesting that an inmate with a thiopental blood levels of 7 mg/L has fifty percent chance of consciousness during their execution. Yet Ronnie Howard had a thiopental blood level so low it could not be measured. Similarly, Kevin Dean Young had a thiopental level of 3.4 mg/L, Michael Passaro had a thiopental level of 6.1, and Larry Gilbert had a thiopental level of 7.1 mg/L. Other thiopental blood levels measured in North Carolina executions (which injects twice the amount of thiopental then Maryland) reveal a similar wide distribution of thiopental blood values including those which, as in South Carolina likewise suggest the inmate was conscious during the execution. (Michael Earl Sexton – 3.7 mg/L, Desmond Keith Carter – trace, James R. Edwards - 2.6 mg/L).

38. The information available to me about Maryland's lethal injection execution protocol contains no reference to plans for dealing with the foreseeable circumstance wherein intravenous access cannot be obtained in the arm or leg. In this setting, state lethal injection protocols typically specify the use of a "cut-down" procedure to access a vein adequate for the reliable infusion of the lethal drugs; a procedure that has been used in at least one lethal injection in Maryland. Based on my medical training and experience, and based on my research into lethal injection procedures and practices, it is my opinion to a reasonable degree of medical certainty that any reliable, humane lethal injection procedure must account for the foreseeable circumstance of a condemned inmate having physical characteristics that prevent intravenous access from being obtained by a needle piercing the skin and entering a superficial vein suitable for the reliable delivery of drugs. Maryland's Execution Procedures provide no information regarding the training, experience, expertise, credentials, certification, or proficiency of the personnel who would perform the "cut down" procedure. Performance of a "cutdown" requires personnel who are specifically proficient in this procedure. The failure to specify the training and proficiency of this individual exposes the inmate to the risk of unnecessary pain and injury, and may even result in death from hemorrhage or other complications.

39. Based on my research into methods of lethal injection used by various states and the federal government, and based on my training and experience as a medical doctor specializing in anesthesiology, it is my opinion based on a reasonable degree of medical certainty that, given the apparent absence of a central role for a properly trained medical or veterinary professional in Maryland's execution procedure, it can and should be presumed that the lethal injection procedure Maryland employs creates medically unacceptable risks of infliction excruciating pain and suffering on inmates during the lethal injection procedure.

FURTHER AFFIANT SAYETH NAUGHT.

I declare under penalty of perjury that everything I have said in the above document captioned AFFIDAVIT OF MARK J. S. HEATH, M.D., BOARD CERTIFIED ANESTHESIOLOGIST is true to the best of my knowledge.

_____

Mark J. S. Heath, M.D., AFFIANT

Sworn to and subscribed before me on this ____ day of May, 2004.

_____

NOTARY PUBLIC

Exhibit 115: Affidavit of Dr. Dennis Geiser, in the case of Texas v. Jesus Flores, No. 877,994A

AFFIDAVIT OF DR DENNIS GEISER, PROFESSOR OF VETERINARY SCIENCE

STATE OF TEXAS V JESUS FLORES

NO. 877994A

IN THE COUNTY OF Knox }

THE STATE OF TENNESSEE }

BEFORE ME, the undersigned authority, did personally appear Dr. Dennis Geiser, and having been duly sworn, did state upon his oath the following:

"My name is Dr Dennis Geiser. I am a professor of veterinary science at the University of Tennessee and the Chairman of the Department of Large Animal Clinical Sciences at the College of Veterinary Medicine at the University of Tennessee.

Pancuronium Bromide is Prohibited in the Euthanasia of Animals

It is significantly below the standard of acceptable practice to use an injection of a neuromuscular blocking agent (of which Pancuronium Bromide is one) for animal euthanasia. The use of that drug is outlawed in a number of States. The use of that drug is inhumane because neuromuscular blocking agents do not produce depression of the central nervous system that would results in anesthesia or analgesia These agents produce a peripheral paralysis of skeletal muscles, rendering an individual unable to respond to external stimuli while still being able to perceive pain and discomfort.

The use of pancuronium bromide is strictly prohibited by the ethical standards of the American Veterinary Medical Association which apply throughout the country. Under the American Veterinary Medical Association standards, there is no allowance for the use of pancuronium bromide in euthanasia under any set of circumstances.

Sodium Thiopental is Not a Proper Anesthetic

Sodium thiopental is not a proper anesthetic for use in lethal injection. Indeed, the American Veterinary Medical Association standards for euthanasia indicate that the ideal barbituric acid derivative for use in euthanasia should be potent, long acting, stable in solution, and inexpensive. Sodium pentobarbital (not sodium thiopental) best fits this criteria. Sodium pentothal is a potent barbituric acid derivative but very short acting with one therapeutic dose.

The AVMA guidelines also state that the use of sodium pentobarbital and neuromuscular blocking agent is an unacceptable euthanasia procedure in animals.

All of the foregoing is true and correct."

Signed: _____

Dr Dennis Geiser
University of Tennessee

SWORN AND SUBSCRIBED BEFORE ME this 12 day of November, 2003

Signed: _____

Notary Public in and for the State of Tennessee

My commission expires June 28, 2006

Exhibit 116: Affidavit of Dr. Dennis Geiser, in the case of Abu-Ali Abdur' Rahman v. Bell, 226 F.3d 696 (6th Cir. 2000)

AFFIDAVIT OF DR. DENNIS GEISER

Dr. Dennis Geiser, being duly sworn, states under oath as follows:

1. I am a doctor of veterinary medicine (D.V.M.). I obtained my D.V.M. degree in 1972. I am a Board Certified Diplomat of the American College of Veterinary Practitioners. I am the chairman of the Department of Large Animal Clinical Sciences at the College of Veterinary Medicine at the University of Tennessee in Knoxville. I specialize in the anesthesiology of large animals.

2. I have been advised that for purposes of carrying out an execution by means of lethal injection in Tennessee, the Tennessee Department of Correction intends to follow a protocol using three drugs in sequence: Sodium Pentothal, an ultra short-acting barbiturate; Pavulon, a curariform mixture and neuromuscular blocking agent; and Potassium Chloride a cardiac arrest agent.

3. The use of peripheral neuromuscular blocking agents alone without adequate adjunct anesthetic agents may cause unnecessary untoward side effects. While Pavulon paralyzes skeletal muscles, including the diaphragm, it has no effect on consciousness or the perception of pain and suffering. It would be like being tied to a tree, having darts thrown at you, and feeling the pain without any ability to respond.

4. The use of Sodium Pentothal as the general anaesthetic poses special risks. The dosage must be measured with some degree of precision, and the administration of the proper amount of the dosage will depend on the concentration of the drug and the size and condition of the subject. Additionally, the drug must be administered properly so that the full amount of the

dosage will directly enter the subject's blood stream at the proper rate. If the dosage is not correct, or if the drug is not properly administered, then it will not adequately anesthetize the subject, and the subject may experience the untoward effects of the neuromuscular blocking agent used. Additionally, under Sodium Pentothal the anaesthetic effect is extremely short-lived, and will be effective for surgical restraint and anesthesia for a period of only five to seven minutes. The duration of action is somewhat dose dependent as well as dependent on the condition of the subject.

5. The American Veterinary Medical Association has declared that it is unacceptable to use peripheral neuromuscular blocking agents for purposes of euthanasia. In my experience, neuromuscular blocking agents have not been in general use for euthanizing animals for many years. I also understand that in Tennessee it is unlawful to use neuromuscular blocking agents for euthanizing non-livestock animals.

FURTHER THE AFFIANT SAITH NOT.

Dennis Geiser, DVM

Sworn to and subscribed before me,

a Notary Public,

This the 5 day of April, 2002.

My commission expires: 11-4-03

Exhibit 117: Affidavit of Carol Weihrer, in the case of Texas v. Jesus Flores, No. 877,994A

AFFIDAVIT OF CAROL WEIHRER

STATE OF TEXAS V JESUS FLORES

NO. 877994A

IN THE COUNTY OF FAIRFAX }

THE STATE OF VIRGINIA }

BEFORE ME, the undersigned authority, did personally appear Carol Weihrer, and having been duly sworn, did state upon her oath the following:

"My name is Carol Weihrer. I underwent an eye operation in which full general anesthesia was administered but the brain scrambling drugs were not effective. I therefore experienced what has come to be known as Anesthesia Awareness, in which I was able to think lucidly, hear, perceive and feel everything that was going on during the surgery, but I was unable to move. It burnt like the fires of hell. It was the most terrifying, torturous experience you can imagine. The experience was worse than death.

To the best of my knowledge, all of the foregoing is true and correct."

Signed: Carol Weihrer

Carol Weihrer
President and Founder
Anesthesia Awareness Campaign, Inc.
http://www.anesthesiaawareness.com

SWORN AND SUBSCRIBED BEFORE ME this 16th day of November, 2003

Signed: _____

Notary Public in and for the State of Virginia